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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA-2019-N-3065]

RIN 0910-AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to establish new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. FDA is taking this action to promote greater public understanding of the negative health consequences of cigarette smoking.

DATES: This rule is effective June 18, 2021. The incorporation by reference of a certain publication listed in the rule is approved by the Director of the Federal Register as of June 18, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of the final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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I. Executive Summary

A. Purpose of the Final Rule

The final rule establishes new required warnings for cigarette packages and advertisements. These new cigarette health warnings consist of textual warning statements accompanied by color graphics depicting the negative health consequences of cigarette smoking.¹

Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined. In issuing the final rule, FDA determined that the public holds misperceptions about the health risks caused by smoking and that textual warning statements focused on less-known health consequences of smoking paired with concordant color graphics will promote greater public understanding of the risks associated with cigarette smoking, especially given that the existing Surgeon General's warnings currently used in the United States go unnoticed and are effectively "invisible." FDA has determined that

¹ For the purposes of discussion throughout this document, FDA uses the terms "cigarette health warnings" to refer to the required warnings and "textual warning statements" to refer to the textual warning label statements.

the required new cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

B. Summary of the Major Provisions of the Final Rule

The final rule establishes new required warnings to appear on cigarette packages and in cigarette advertisements. The rule implements a provision of the Tobacco Control Act that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the FCLAA to require each cigarette package and advertisement to bear one of the new required warnings. These new cigarette health warnings consist of textual warning statements accompanied by color graphics, in the form of concordant photorealistic images, depicting the negative health consequences of cigarette smoking. As required by section 4 of the FCLAA, the new cigarette health warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

In addition, as required under the FCLAA, the final rule establishes marketing requirements that include the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotation of the required warnings for cigarette advertisements. A tobacco product manufacturer, distributor, or retailer is required to submit a plan for the random and equal display and distribution of the required warnings on packages and the quarterly rotation in advertisements for approval by FDA. In addition, each tobacco product manufacturer that is required to randomly and equally display and distribute required warnings on packaging and quarterly rotate required warnings in advertisements, in accordance with an

FDA-approved plan, also must maintain a copy of the FDA-approved plan and make the plan available for inspection and copying by officers and employees of FDA.

FDA developed the new cigarette health warnings included in the final rule through a science-based, iterative research process. The required warnings will promote greater public understanding of the negative health consequences of cigarette smoking.

C. Legal Authority

The final rule is being issued in accordance with sections 201 and 202 of the Tobacco Control Act (Pub. L. 111-31), which amend section 4 of the FCLAA (15 U.S.C. 1333). The final rule is also being issued based upon FDA's authorities related to misbranded tobacco products under sections 903 (21 U.S.C. 387c); FDA's authorities related to records and reports under section 909 (21 U.S.C. 387i); and FDA's rulemaking and inspection authorities under sections 701 (21 U.S.C. 371), 704 (21 U.S.C. 374), and 905(g) (21 U.S.C. 387e(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs and Benefits

This final rule requires that new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, appear on cigarette packages and in cigarette advertisements. The final rule further requires that, for cigarette packages, these required warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product, and be randomly and equally distributed throughout the United States in accordance with a plan approved by the FDA. The final rule also requires that, for cigarette advertisements, the required warnings be rotated quarterly in alternating sequences in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. The final new cigarette health warnings will promote greater public understanding of the

negative health consequences of cigarette smoking by presenting information about the health risks of smoking to smokers and nonsmokers in a format that helps people better understand these consequences. We describe economic benefits qualitatively. The cost of this final rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. We estimate that, at the mean, the present value of the costs of this final rule is about \$1.6 billion using a three percent discount rate and roughly \$1.2 billion using a seven percent discount rate (2018\$). If the information provided by the cigarette health warning on each cigarette package were valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs. This per-pack estimate provides one way to estimate the value the public would need to receive from the information provided on the cigarette health warnings in order to break even with the costs of the rule and is equivalent to 0.2 percent of the average cost of a pack of cigarettes, based on a national average cost of \$6.27 per pack.²

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/Acronym	What It Means
APA	Administrative Procedure Act

² FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 11-week period ending March 23, 2019, for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See <http://www.nielsen.com/us/en.html> for more information.

CABG	Coronary artery bypass grafting
CDC	Centers for Disease Control and Prevention
COPD	Chronic obstructive pulmonary disease
CVD	Cardiovascular disease
D.C. Cir.	United States Court of Appeals for the District of Columbia Circuit
EO	Executive Order
EPA	Environmental Protection Agency
EPS	Encapsulated PostScript
FCLAA	Federal Cigarette Labeling and Advertising Act
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration or Agency
FR	Federal Register
HHS	U.S. Department of Health and Human Services
NARA	National Archives and Records Administration
NIFLA	Nat'l Inst. of Family and Life Advocates
NSDUH	National Survey on Drug Use and Health
OMB	Office of Management and Budget
PAD	Peripheral arterial disease
PATH	Population Assessment of Tobacco and Health
PCI	Percutaneous coronary interventions
PDF	Portable document format
PMTA	Premarket tobacco product application
PVD	Peripheral vascular disease
SAMHSA	Substance Abuse and Mental Health Services Administration
SES	Socioeconomic status
TCA statements	Textual warning statements specified in section 4(a)(1) of the FCLAA
TTB	Alcohol and Tobacco Tax and Trade Bureau
WHO	World Health Organization

III. Background

A. Introduction

To help inform consumers of the potential hazards of cigarette smoking, Congress passed the FCLAA that required that a printed text-only warning appear on cigarette packages (Pub. L. 89-92). The 1965 warning requirement was modified by later amendments to the FCLAA, including the Comprehensive Smoking Education Act of 1984 (Pub. L. 98-474), which extended the warning requirement to cigarette advertising and updated the one warning to four warnings, frequently referred to as the Surgeon General's warnings.

The FCLAA has required the inclusion of text-only warnings on cigarette packages and in cigarette advertisements for many years. As discussed in detail in the proposed rule (84 FR 42754, August 16, 2019) (hereinafter referred to as the proposed rule), there is considerable evidence that the Surgeon General's warnings go largely unnoticed and unconsidered by both smokers and nonsmokers (Ref. 1 at p. 291; see also section V of the proposed rule). These warnings, which have not changed in 35 years, have been described as "invisible" (Ref. 2) and fail to convey relevant information in an effective way (Ref. 1 at p. 291). The Surgeon General's warnings also do not include any color graphics.

In 2009, in enacting the Tobacco Control Act, Congress further amended the FCLAA and directed FDA to issue new cigarette health warnings that would include a graphic component depicting the negative health consequences of smoking to accompany the new textual warnings (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act).

As discussed in the proposed rule, the health risks associated with cigarette smoking are significant. In developing new cigarette health warnings for the final rule, FDA carefully examined the scientific literature, including the 2014 Surgeon General's Report (Ref. 3), which identified 11 more health conditions that have been established to have sufficient evidence to infer a causal link to cigarette smoking--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports. Those health conditions examined in the 2014 Surgeon General's Report are in addition to the more than 40 unique health consequences already classified in previous Surgeon General's Reports as being caused by smoking and

exposure to secondhand smoke. Additional findings in the scientific literature demonstrate that the U.S. public--including youth and adults, smokers and nonsmokers--holds misperceptions about the health risks caused by smoking (Refs. 4–10). Through its review of the scientific literature, as well as the Agency's science-based, iterative research and development process (see section VI of the proposed rule), FDA determined that having warning statements focused on less-known health consequences of smoking accompanied by photorealistic images would promote greater public understanding of the risks associated with cigarette smoking, especially given the unnoticed and "invisible" 1984 Surgeon General's warnings currently used in the United States.

Therefore, consistent with section 4 of the FCLAA (as amended by sections 201 and 202 of the Tobacco Control Act), we are finalizing a set of 11 required warnings, consisting of textual warning statements accompanied by concordant color graphics depicting the negative health consequences of smoking, to appear on cigarette packages and in cigarette advertisements. Specifically, we are replacing part 1141 to Title 21 of the Code of Federal Regulations (21 CFR Part 1141), and the new part 1141 requires new cigarette health warnings on cigarette packages and in cigarette advertisements. As required by section 4 of the FCLAA, the new cigarette health warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

As described in the preamble to the proposed rule and in the final rule, FDA has determined that the new required cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

On August 16, 2019, FDA issued a proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements. These proposed cigarette health warnings consisted of a set of textual warning statements to be accompanied by concordant color graphics depicting the negative health consequences of smoking. FDA proposed to take this action to promote greater public understanding of the negative health consequences of cigarette smoking as directed by sections 201 and 202 of the Tobacco Control Act (amending section 4 of the FCLAA). FDA received about 300 comments to the docket for the proposed rule. Comments were received from cigarette manufacturers, retailers and retailer organizations, representatives of tribes/tribal organizations, health professionals and researchers, public health or other advocacy groups, academics, State and local public health agencies, medical organizations, individual consumers, and other submitters. These comments are summarized and responded to in the relevant sections of this document. Similar comments are grouped together by the topics discussed or the particular portions of the proposed rule or codified language to which they refer.

To make it easier to identify comments and FDA's responses, the word "Comment," in parenthesis, appears before the comment's description, and the word "Response," in parenthesis, appears before FDA's response. Each comment is numbered to help distinguish among different comments, and the number assigned is purely for organizational purposes and does not signify value or importance. Similar comments are grouped together under the same comment number. In addition to the comments specific to this rulemaking that we address in the following sections, we received many general comments expressing support or opposition to the rule and separate provisions within the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. The remaining comments, as well as FDA's responses, are included in this document.

B. Incorporation by Reference

FDA is incorporating by reference "Required Cigarette Health Warnings, 2020," which was approved by the Office of the Federal Register. You may obtain a free copy of the material from FDA's website, located at <https://www.fda.gov/cigarette-warning-files>; the Docket at <https://www.regulations.gov>; or from the Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, email: cigarettewarningfiles@fda.hhs.gov.

The material incorporated by reference, entitled "Required Cigarette Health Warnings, 2020," includes the required warnings (comprising a textual warning statement, as specified in § 1141.10(a), and its accompanying color graphic) in different layouts based on the size and aspect ratio of the display area where the required warning must appear (i.e., on cigarette packages, in cigarette advertisements). We have included an electronic portable document format (PDF) file containing all the required warnings as a reference in the docket for the final rule (Ref. 11). FDA is also making this material available on its website at <https://www.fda.gov/cigarette-warning-files>.

FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and sizes of cigarette packages and advertisements. To help prevent distortion of the image and text and to minimize the need for adaptation, FDA has created electronic, layered design files, built as Encapsulated PostScript (.eps) files, in different formats and aspect ratios designed to fit packaging and advertising of various shapes and sizes. FDA is not requiring the use of these .eps files, but rather we are providing the files as a resource to assist regulated entities implement part 1141. In addition to the material incorporated by reference and the .eps files, FDA is making available a

technical specifications document that includes information on how to access, select, use, and adapt the appropriate .eps file based on the size and aspect ratio of the display area where the required warning must appear. These .eps files and technical specifications are also available on FDA's website at <https://www.fda.gov/cigarette-warning-files>.

IV. Legal Authority

A. Summary of Legal Authority

As set forth in the preamble to the proposed rule, the Tobacco Control Act amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the FCLAA to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements and directs the Secretary of the Department of Health and Human Services³ to "issue regulations that require color graphics depicting the negative health consequences of smoking" to accompany the nine new health warning statements. Congress also provided that the provision requiring the new health warning statements would not become effective until after the graphic label rulemaking was completed. Under section 201 of the Tobacco Control Act, in a subsection entitled "Graphic Label Statements," FDA may adjust the type size, text, and format of the cigarette health warnings as FDA determines appropriate so that both the color graphics and the accompanying textual warning statements are clear, conspicuous, and legible and appear within the specified area (15 U.S.C. 1333(d)).

Section 202(b) of the Tobacco Control Act, in a subsection entitled "Change in Required Statements," also amends section 4 of the FCLAA to add a new subsection that permits FDA,

³ The Secretary has delegated this authority to FDA. For the purposes of discussion throughout this document, FDA uses "FDA" when discussing this authority.

through a rulemaking, to adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the FD&C Act, if such a change would promote greater public understanding of the risks associated with the use of tobacco products (15 U.S.C. 1333(d)).⁴ Such adjustments, including adjustments to the text of some of the warning statements and to the number of required warnings, were included as part of the proposed rule.

These requirements are supplemented by the FD&C Act's misbranding provisions, which require that product labeling and advertising include required warnings (section 903). Under section 701(a) of the FD&C Act, FDA has authority to issue regulations for the efficient enforcement of the FD&C Act, and sections 704 and 905(g) provide FDA with general inspection authority.

Section 909 of the FD&C Act authorizes FDA to require tobacco product manufacturers to establish and maintain records, make reports, and provide such information as the Agency may by regulation reasonably require to ensure that a tobacco product is not adulterated or misbranded and to otherwise protect public health.

While FDA did not receive comments on many of these authorities, FDA did receive comments regarding our authority to require more than nine warning label statements and to adjust the text, as well as comments related to the Administrative Procedure Act (APA) and the constitutionality of the required warnings. These comments are summarized and responded to in the following paragraphs. Multiple comments are often summarized together for convenience.

⁴ Section 201(a) of the Tobacco Control Act amends section 4 of the FCLAA to add a new subsection (d), "Graphic Label Statements," which is codified at 15 U.S.C. 1333(d). Section 202(b) of the Tobacco Control Act amends section 4 of the FCLAA to also add a new subsection (d), "Change in Required Statements," which is also codified at 15 U.S.C. 1333(d). Both provisions of the Tobacco Control Act are correctly codified as "15 U.S.C. 1333(d)." To reduce confusion, this document refers to them, respectively, as section 201 and section 202(b).

Comment numbers are assigned to facilitate later reference; they do not indicate importance or the sequence in which comments were received.

B. Comments Regarding Legal Authority

(Comment 1) FDA received several comments, including comments from cigarette manufacturers and a retail organization, disputing FDA's authority to adjust the text of the warning label statements, to propose textual warning statements other than the nine warnings included in section 201 of the Tobacco Control Act (amending section 4 of the FCLAA), and to require more than nine warning label statements. These comments argue that section 202(b) only permits FDA to adjust the format and type size for the label statement, which does not include rewriting and replacing the Tobacco Control Act warning label statements. Instead, FDA should have proposed warnings that used only the text statements that Congress set out in section 201 of the Tobacco Control Act.

(Response 1) FDA disagrees with these comments. When Congress passed the Tobacco Control Act, Congress also amended the FCLAA to give the Secretary more specific authority to adjust and revise required cigarette warnings. This new authority includes two separate provisions authorizing FDA to revise aspects of the warning statements:

- Section 201 of the Tobacco Control Act, which provides that the Secretary "may adjust the type size, text and format of the label statements *specified in [FCLAA] subsections 4(a)(2) and 4(b)(2)* as the Secretary determines appropriate so that both the graphics and accompanying label statements are clear, conspicuous, legible and appear within the specified area;" and
- Section 202(b), which permits the Secretary, through a rulemaking, to "adjust the format, type size, color graphics, and text of any of the label requirements . . . if the Secretary

finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products." (Emphasis added.)

It is significant that section 201 cross-references subsections (a)(2) and (b)(2); subsection (a)(2) addresses "Placement; typography; etc." for the "label statement[s] required by paragraph [(a)(1)]" for package labels, and subsection (b)(2) addresses the "Typography, etc." of the "label statement[s] required by subsection (a)" for cigarette advertising. Thus, the adjustments authorized by section 201 focus on placement, typography, clarity, conspicuousness, and legibility--changes that go to the visual presentation of cigarette warnings. By contrast, section 202(b) gives the Secretary broader authority to "adjust the format, type, size, color graphics, and text of any of the label *requirements*" (emphasis added). Section 202(b)'s reference to "label requirements" is also significant; at minimum, it refers to and sweeps in the entirety of FCLAA subsection 4(a), which is entitled "Label Requirements." Also importantly, section 202(b) allows its more sweeping adjustments only upon a finding that "such a change would promote greater public understanding of the risks" of smoking.

The adjustments permitted by section 202(b) therefore differ from those permitted by section 201 in that:

(1) section 202(b) authorizes adjustments to "any of the label *requirements*" of FCLAA subsection 4(a), rather than just adjustments to the "type size, text and format" specified in FCLAA subsection 4(a)(2) (governing the placement, typography, etc., of the "label statements" on package labels) and (4)(b)(2) (governing the typography, etc., of the "label statements" in cigarette advertising);

(2) the relevant finding relates to promoting the public's understanding of the risks associated with the use of tobacco products rather than the visual clarity of the label statements; and

(3) section 202(b) explicitly requires rulemaking under 5 U.S.C. 553 for the adjustments it authorizes, while section 201 does not.

We therefore disagree with comments that argue that, under section 202(b), FDA may only adjust the typographic look of the warnings' text, not their substance. That assertion conflicts with the plain meaning of "text," which, as comments concede, refers to both "words and form," not merely the latter. The interpretation is also inconsistent with the difference in the predicate findings required for adjustments under sections 201 and 202(b): visual clarity versus improving public understanding of risks. If Congress had meant section 202(b) to limit FDA to making adjustments to improve visual clarity, it would not have included a predicate finding that relates to the warnings' substance. Congress further indicated its intent to allow more substantive changes under section 202(b) by explicitly requiring rulemaking under 5 U.S.C. 553, while adjustments under section 201 are allowed simply upon the Secretary's determination.

Some comments argue that the term "adjust" precludes changes that would better be described by the term "edit" or "revise." FDA disagrees. First, the title of section 202 of the Tobacco Control Act is "Authority to *Revise* Cigarette Warning Label Statements" (emphasis added). That title reflects Congress's intent to authorize FDA to revise the warning statements themselves, not merely make typographical changes. Second, section 202(b) includes the authority to adjust not only the text of the warnings but also non-textual items like "format," "type size," and "color graphics"--"edit" or "revise" would not as clearly encompass the types of changes associated with those items. It is therefore likely that Congress chose the term "adjust"

as an umbrella term best suited to include the variety of changes authorized under section 202(b) of the Tobacco Control Act.

FDA also disagrees with the comments that asserted that Congress did not authorize FDA to adjust the number of warnings. As discussed below, it is far from clear that the number of warnings is in fact a statutory requirement. But even if it were, the statutory language does not speak directly to this issue, and FDA reasonably construes the statute to allow it to adjust the number of warnings. Section 202(b) of the Tobacco Control Act authorizes FDA to adjust the "text of any of the label *requirements*" if such a change would promote greater public understanding of the risks associated with the use of tobacco products--not just to adjust the "types size, text and format of the label *statements*" specified in subsections governing "placement, typography, etc." so that both the graphics and the accompanying label statements are clear, conspicuous, legible, and appear within the specified area, as section 201 does (emphasis added).

As amended by the Tobacco Control Act, subsection 4(a) of the FCLAA, which identifies the "label requirements" that may be adjusted under section 202(b), does not provide a requirement as to how many warnings there must be. Nothing in the head of subsection 4(a)(1) refers to "9 labels"; rather, it refers to "one of the following labels." In addition, section 202(a) of the Tobacco Control Act amends the FCLAA's preemption provision, subsection 5(a) of the FCLAA, to provide that, "Except to the extent the Secretary requires *additional* or different statements on any cigarette package by a regulation, . . . no statement relating to smoking and health, other than the statement required by section 4 of [the FCLAA, now amended by the Tobacco Control Act], shall be required on any cigarette package." FCLAA subsection 5(a), as amended by Tobacco Control Act section 202(a) (codified at 15 U.S.C. 1334(a)) (emphasis

added). The reference to "additional" statements indicates that Congress did not consider nine warnings to be a fixed statutory requirement. In any event, by authorizing adjustments to the "text of any of the label requirements," section 202(b) plainly contemplates that FDA may adjust the "text" of the label requirements within paragraph (1) of subsection 4(a) of the FCLAA (which is entitled "Label Requirements"), precisely as this final rule does.

Even if FCLAA subsection 4(a)(1) required "one of the following 9 labels," and not just "one of the following labels," as it actually does, such a numeric requirement would still be among the FCLAA "label requirements" subject to being adjusted under section 202(b) of the Tobacco Control Act. FDA has determined that all 11 warnings that are part of this final rule will promote greater public understanding of the risks of cigarette smoking. FDA therefore may adjust the number of warnings through this rulemaking conducted under 5 U.S.C. 553.

(Comment 2) One comment states that FDA does not have the authority to change the textual statements provided in the Tobacco Control Act without implementing them first.

(Response 2) FDA disagrees. Under section 202(b), FDA may, through a rulemaking, adjust the format, type size, color graphics, and text of any of the label requirements if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products. Nothing in the language of section 202(b) of the Tobacco Control Act requires the Agency to first issue warnings with the Tobacco Control Act statements, and then wait 15 months or more for such warnings to be implemented, before the Agency may embark on an effort to revise the warning statements. What the statute requires is that revisions to the textual warning statements specified in section 4(a)(1) of the FCLAA ("TCA statements") be based on a finding that such a change would promote greater public understanding of the risks of smoking. Accordingly, in considering whether to revise the

warnings, FDA designed and undertook a rigorous science-based, iterative research process specifically to assess whether new textual warning statements would promote greater public understanding of the risks associated with tobacco products compared to the warning statements provided in the Tobacco Control Act. As part of its research, FDA conducted a large (2,505 participants) quantitative consumer research study (OMB control number 0910-0848, "Experimental Study on Warning Statements for Cigarette Graphic Health Warnings"). This first consumer research study evaluated new textual warnings statements compared to the warning statements provided in the Tobacco Control Act to determine if they would promote greater understanding of the risks of smoking. More details about the study methodology can be found in the study report included in the docket (Ref. 12). The results show that, with respect to the outcomes most predictive for demonstrating greater understanding of the risks of smoking--"new information" and "self-reported learning"--nearly all tested new textual warning statements performed significantly better than nearly all textual warning statements provided by the Tobacco Control Act. The results of this first consumer research study informed the selection of textual warning statements that FDA then paired with concordant images for testing in a final consumer research study (OMB control number 0910-0866, "Experimental Study of Cigarette Warnings") (see section VI for more discussion about FDA's approach to developing and testing cigarette health warnings). FDA has therefore complied with section 202(b) by including new textual warnings in the final rule only after finding that they will promote greater public understanding of the risks associated with smoking as compared to certain textual warnings in the Tobacco Control Act that are excluded from the final rule.

C. Comments Regarding First Amendment Considerations

FDA received comments from industry, retailers, public health organizations and coalitions, state and local governments, academia, and private citizens related to First Amendment considerations. Several comments from manufacturers, retail organizations, and private citizens assert that the required warnings violate the First Amendment of the United States Constitution under a variety of legal standards. Several other comments, including from public health organizations and state and local governments, state that the required warnings comport with First Amendment requirements.

1. Government's Interest

(Comment 3) Some comments suggest that the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking is not substantial, and that, in any case, FDA's Population Assessment of Tobacco and Health (PATH) data and public health campaigns undermine that asserted interest. Related comments suggest that, under the Supreme Court's decision in *Nat'l Inst. of Family and Life Advocates (NIFLA) v. Becerra*, 138 S. Ct. 2361 (2018), the Government may not compel "unjustified disclosures," such as disclosures that fail to address a harm that is potentially real and not purely hypothetical, or that fail to remedy the harm, e.g., by telling people things they already know.

Other comments state that "communicat[ing] health information to the public about the negative health effects of cigarettes" is not the Government's interest, because the Tobacco Control Act identifies the Government's interest as reducing the number of youth and adults that use cigarettes. These comments assert that FDA should not proceed unless FDA demonstrates the new text and color graphics will reduce smoking rates. Similarly, other comments assert that, as with the 2011 final rule (76 FR 36628, June 22, 2011), FDA's "true" governmental interest is to reduce smoking and that FDA has not provided any evidence in support of that interest. Other

comments generally support FDA's interest in promoting greater public understanding of the negative health consequences as a substantial Government interest that fully supports the rule.

(Response 3) FDA agrees with the comments that recognize that promoting greater public understanding of the negative health consequences of smoking is a substantial Government interest that fully supports the rule. Providing relevant, truthful, and non-misleading information to consumers in ways that promote greater public understanding provides consumers with a better opportunity to make informed choices. *See, e.g., Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 184-85 (1999); Ref. 13 at 405 ("Disclosure requirements are based on the 'informational function' of commercial speech and the accepted understanding that it would be impossible for consumers to verify such information on their own. As a result, the U.S. regulatory landscape is replete with commercial disclosure requirements.").

As the Sixth Circuit concluded, "[t]here can be no doubt that the government has a significant interest in . . . warning the general public about the harms associated with the use of tobacco products." *Discount Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 519 (6th Cir. 2012). Cigarette smoking remains the primary cause of preventable disease and death in the United States. The magnitude of this public health crisis is compounded by the gaps in knowledge and misperceptions held by smokers and nonsmokers about the wide variety of negative health consequences caused by smoking.

Moreover, FDA's research confirms that the public continues to hold misperceptions about the health risks of smoking and is largely unaware of certain serious conditions caused by smoking (see section V.B; see also NPRM section V.A.3, 84 FR at 42761-62 ("There Remain Significant Gaps in Public Understanding About the Negative Health Consequences of Cigarette Smoking")). Contrary to some comments' assertions, consumers suffer from a pervasive lack of

knowledge about the negative health consequences of smoking, as both smokers and nonsmokers do not fully understand that smoking is causally linked to a wide variety of diseases and health conditions (see section V.B).

We disagree with comments that argue the public's knowledge of the general harms of cigarette smoking undercuts the need for these required warnings. As clearly demonstrated by the rulemaking record, both the harms of cigarette smoking thoroughly detailed in years of Surgeon General's reports, and the widespread public misperceptions about these harms, are very "real not purely hypothetical." *NIFLA*, 138 S. Ct. at 2377.

Congress has long recognized and taken steps to address this information gap. As far back as 1965 when Congress first passed the FCLAA, it set forth the policy of a comprehensive warning program on cigarette packages and advertisements so that "the public may be adequately informed" about the dangers of cigarette smoking. FCLAA Section 2(1), codified at 15 U.S.C. 1331(1). When Congress amended the FCLAA with the Tobacco Control Act, it recognized that the current 1984 Surgeon General's warnings had become "ineffective in providing adequate warnings about the dangers of tobacco products" (Ref. 14 at 4). To that end, Congress mandated new cigarette warnings to be accompanied by color graphics and provided the Secretary with the authority to adjust such warning label requirements if "such a change would promote greater public understanding of the risks associated with the use of tobacco products" (section 202(b) of the Tobacco Control Act).

Under the framework set out in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), which FDA believes is applicable here, a Government interest supporting factual disclosures need not be substantial. But even if a substantial interest were required, that standard is easily met for these required warnings. "[T]here is no question that [the Government's] interest

in ensuring the accuracy of commercial information in the marketplace is substantial." *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 415 (D.C. Cir. 2012). That interest is heightened when the information at issue concerns the health risks inherent in using a product. *See Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 341 (1986) ("[H]ealth, safety, and welfare constitute a 'substantial' governmental interest"); *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir.) ("There is no question that protecting the health and safety of consumers is a substantial governmental interest."), *cert. denied*, 205 L. Ed. 2d 387 (Dec. 9, 2019). As discussed in further detail in the preamble to the proposed rule, as well as in section VII below, the required warnings provide factual and accurate information about the products that are subject to them. The disclosure of factual and accurate information promotes greater consumer understanding about their choices in the marketplace. Because "tobacco products are dangerous to health when used in the manner prescribed," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 135 (2000), the Government has a substantial interest in requiring disclosures providing factual and accurate information about the negative health consequences of such products to promote greater public, including consumer, understanding.

FDA also does not agree with comments asserting that the Agency's one true interest lies in reducing smoking rates. The comments cite to Congressional findings in the Tobacco Control Act, which indicate that Congress's purposes for the Tobacco Control Act *as a whole* include reducing the use of tobacco by minors in an effort to protect millions from suffering premature death due to tobacco-induced disease. However, with respect to the warning requirements for cigarettes, the statute itself is specific: the required warnings are to "depict[] the negative health consequences of smoking" and any changes to these label requirements are to "promote greater

public understanding of the risks associated with the use of tobacco products" (sections 201 and 202 of the Tobacco Control Act).

2. *Zauderer*

In the proposed rule, FDA explained that this rule would be properly analyzed under the *Zauderer* standard, under which the Government may require the disclosure of factual and uncontroversial information in commercial marketing where the disclosure is justified by a governmental interest and does not unduly burden protected speech. FDA received many comments addressing the applicability of the First Amendment standard set out in *Zauderer*.

Some of the comments suggest that the required warnings FDA proposed cannot be upheld under *Zauderer* because they are not required to remediate any misleading commercial speech or disclose information about the terms under which services are available; do not provide purely factual and uncontroversial information; and are unjustified, unduly burdensome, and not reasonably related to a substantial Government interest. Other comments from public health organizations and academia support the required warnings as appropriate under the First Amendment and specifically under *Zauderer* because these are mandatory factual disclosures that convey valuable factual information to consumers.

a. Applicability of *Zauderer*.

(Comment 4) Some comments argue that the proposed warnings should not be subject to evaluation under *Zauderer* because they are not being issued to address consumer deception.

(Response 4) FDA disagrees that *Zauderer* applies only to disclosures that seek to address consumer deception. The comments to the contrary highlight the "preventing deception" phrase at the end of this passage in *Zauderer*: "we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in

preventing deception of consumers." *Zauderer*, 471 U.S. at 651. But this passage merely references "the State's interest" in the particular case before the Court, which contended that advertisements without certain disclosures were "false or deceptive." *Id.* at 633. The Court made no suggestion that its analysis was confined to mandatory disclosures that seek to prevent deception and no others.

The D.C. Circuit considered and rejected such a limited reading of *Zauderer* in *American Meat Institute v. U.S. Department of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). In *American Meat*, a Department of Agriculture regulation implementing a federal statute required identification of the country of origin on the packaging of meat and meat products. *Id.* at 20. Examining the facts and language at issue in *Zauderer* and *Milavetz, Gallop & Milavetz, PA. v. United States*, 559 U.S. 229, 253 (2010), in which the Court repeated the "preventing deception" language, the D.C. Circuit held that *Zauderer* should not be read to apply only to cases where Government-compelled speech prevents or corrects deceptive speech. *Id.* at 22.

Other circuits addressing this issue have unanimously agreed. In 2001, the Second Circuit applied *Zauderer* and upheld a compelled disclosure supported by a substantial state interest in protecting human health and environment, "intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products," even though it was "not intended to prevent 'consumer confusion or deception' per se." *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (quoting *Zauderer*). *Accord*, *CTIA*, 928 F.3d at 844 (*cert. denied*, 205 L. Ed. 2d 387 (Dec. 9, 2019)) (government interest in furthering public health and safety is sufficient under *Zauderer* so long as it is substantial); *Discount Tobacco*, 674 F.3d at 556-58 (upholding federally required health warnings on cigarette packaging and in cigarette advertisements, citing *Sorrell*); *Pharm. Care Mgmt. Ass'n v. Rowe*,

429 F.3d 294, 310 n. 8 (1st Cir. 2005) (noting that the court had found no cases limiting application of the *Zauderer* compelled speech test to prevention or correction of deceptive advertising); *cf. Dwyer v. Cappell*, 762 F.3d 275, 281-82 (3d Cir. 2014) (describing but not relying on *Zauderer's* preventing-deception criterion). And nothing in *NIFLA* calls those precedents into doubt. *See Am. Bev. Ass'n v. City & City of San Francisco*, 916 F.3d 749, 756 (9th Cir. 2019) (en banc) ("*NIFLA* did not address, and a fortiori did not disapprove, the circuits' precedents . . . , which have unanimously held that *Zauderer* applies outside the context of misleading advertisements.").

The required health warnings are in any event intended in part to correct consumer misperceptions regarding the risks presented by cigarettes, and thereby "to dissipate the possibility of consumer confusion or deception." *Zauderer*, 471 U.S. at 651 (internal quotation marks omitted). There is a long history of deception concerning consumer health risks in the cigarette industry. The 2014 Surgeon General's Report provided a 50-year survey, and the second of its ten "Major Conclusions" was that "[t]he tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes" (Ref. 3 at 7). *See also United States v. Philip Morris USA Inc.*, 566 F.3d 1095 (D.C. Cir. 2009) (upholding racketeering, fraud, and conspiracy findings against the nation's major cigarette companies). Even if the largest players in the industry had not engaged in half a century of fraud, FDA's extensive evidence demonstrates that important consumer misperceptions regarding the nature and degree of the risks presented by these products persist. Therefore, FDA does not agree that *Zauderer* scrutiny is inapplicable here.

(Comment 5) At least one comment argues that the proposed warnings should not be subject to evaluation under *Zauderer* because the Supreme Court in *NIFLA* limited *Zauderer* to cases involving disclosures regarding the provision of services, not goods.

(Response 5) FDA does not agree *Zauderer* is limited to cases involving the provision of services. The Supreme Court in *NIFLA* "d[id] not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial *products*." 138 S. Ct. at 2376 (emphasis added). While the question presented in that case concerned *Zauderer*'s application to services other than those provided by the speaker, *id.* at 2372, nothing in the opinion suggests that the Court intended to limit *Zauderer*'s applicability to *services* to the exclusion of *products*.

b. Factual, accurate, and uncontroversial.

(Comment 6) FDA received comments addressing the factualness and accuracy of the required warnings. Under *Zauderer*, these comments state, a compelled disclosure must be purely factual, and disclosure requirements that are intended to evoke an emotional response, shock the viewer into retaining information, or convey an ideological message about how consumers should behave do not qualify as purely factual. Many of these comments referred to the D.C. Circuit's 2012 decision striking down the pictorial cigarette warnings the Agency issued in 2011, *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). These comments generally imply that any pictorial cigarette warning cannot be factual because the point of the warnings is to force consumers to look at gruesome images that evoke feelings of shame and fear and to convey an ideological message turning cigarette packages and advertisements into mini-billboards for the Government's anti-smoking position. The comments also specifically suggest that the required warnings proposed by FDA are not purely factual because they contain what the

commenters consider shocking and inflammatory images. The comments cite as examples the images of diseased feet with amputated toes, the head and neck tumor, and the lungs, which the comments say are intended to convey emotions of fear, shame, and disgust. The comments also contend that FDA's consumer studies confirm that the required warnings are not factual because the first quantitative consumer research study showed that many of the tested statements were perceived to be less believable than the Tobacco Control Act's warning statements, and in the final quantitative consumer study, eight of the proposed warnings were less likely to be "perceived as factual" than the Surgeon General's warnings.

FDA also received comments that the required warnings proposed by FDA are factual and accurate because the textual statements and accompanying photorealistic images depicting the health harm described or the effect of that harm are supported by a broad consensus of scientific research and U.S. Surgeon General's Reports. The comments point to FDA's final quantitative consumer research study showing that the new text warnings, paired with the accompanying images, provide new information that promotes greater public understanding of the negative health consequences of smoking. These comments also note that there is nothing in the administrative record that suggests the color images are intended to evoke an emotional response instead of illustrating the factual statements. The comments observe that, to the extent any information about actual negative health effects of smoking evokes emotion, that response does not make the information or images any less factual.

Some comments also suggest that the warnings do not provide purely factual and uncontroversial information but instead are misleading because they "do not depict conditions as they are typically experienced by smokers and instead depict procedures or outcomes that are distinct from or extreme as compared to the written warning." Comments state that several of the

images "exaggerate the effects of the diseases they purport to represent, exaggerate the likelihood of those diseases caused by smoking, or offer a misleading portrayal of the treatment of those diseases." Other comments suggest that the required warnings proposed by FDA do not go far enough in visual depiction or textual statement, which results in misleading understatement of the negative health consequences of smoking. Some comments also state that FDA did not develop evidence that the required warnings convey factual information to consumers in a way that is not misleading and suggest the studies were not designed to do so. Comments suggest that the study designs did not evaluate whether any of the warnings FDA proposed conveyed accurate information, and that, for example, unlike FDA's draft recommendations with modified risk tobacco products, FDA failed to evaluate consumer understanding of absolute and relative risk.

(Response 6) FDA disagrees with those comments that suggest the visual depictions are not factual and accurate based on their assertion that they are designed to evoke an emotional response, such as disgust, and agrees with those comments that say the images illustrate the factual and accurate textual statements with which they are paired. In developing the proposed images, FDA conducted a science-based, iterative research process to develop, test, and refine images that were factually accurate; that depicted common visual presentations of the health conditions and/or showed disease states and symptoms as they are typically experienced; that presented the health conditions in a realistic and objective format devoid of non-essential elements; and that study participants found were concordant with the statements on the same health conditions. To do this, FDA staff, including internal medical experts from a range of specialties, worked closely with a certified medical illustrator to develop high quality, factually

accurate photorealistic images (see section VI of the proposed rule, 84 FR at 42765-66, 42770-71).

While there is little guidance from the courts with respect to what constitutes factual and accurate with respect to images for purposes of *Zauderer* scrutiny, some comments have noted that the majority of the resulting images now being included in the final warnings match up with examples of potential factual disclosures given by the Sixth Circuit in *Discount Tobacco*, 674 F.3d 509. In *Discount Tobacco*, the Sixth Circuit provided a non-exhaustive list of the types of images that could pass muster under *Zauderer* as factual and uncontroversial accompanying cigarette warnings. These include, for example, "a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition" (images in the required warnings include a diseased lung); a "picture or drawing of a person suffering from a smoking-related medical condition" (images in the required warnings include persons suffering from cataracts, reduced blood flow, heart disease, erectile dysfunction, respiratory problems, head and neck cancer, and chronic obstructive pulmonary disease (COPD)); or "pictures consisting of text and simple graphic images" (images in the required warnings include an underweight baby on a scale, a urine specimen cup, and a blood glucose monitor). *Discount Tobacco*, 674 F.3d at 559. As the Sixth Circuit noted, medical students look at such pictures or drawings to learn about medical conditions and biological systems because they are factual. *Id.* The images included in the warnings reflect precisely that type of factual content.

FDA also carefully considered the D.C. Circuit's conclusions regarding the Agency's 2011 cigarette warning final rule, including the court's statements criticizing those images as having been designed "to evoke an emotional response" with "inflammatory images and the provocatively-named hotline." *R.J. Reynolds*, 696 F.3d at 1216 (referencing "1-800-QUIT-

NOW" hotline). The Court further found that "many" of the images "could be misinterpreted by consumers." *Id.* (stating that an "image of a man smoking through a tracheotomy hole might be misinterpreted as suggesting that such a procedure is a common consequence of smoking," rather than symbolize the addictive nature of cigarettes, as FDA contended--in other words, consumers might not find the images concordant with their accompanying text statements). The D.C. Circuit additionally found that "many" of the images did "not convey *any* warning information at all." *Id.* (referencing images of a woman crying, a small child, and a man wearing a T-shirt emblazoned with the words "I QUIT"). FDA has addressed those criticisms in several ways. FDA used a certified medical illustrator to design images that depicted common visual presentations of the health conditions and/or showed disease states and symptoms as they are typically experienced, and that present the health conditions in a realistic and objective format devoid of non-essential elements. FDA used different criteria to select and study the images and warnings for this rule than it did in the 2011 rulemaking. FDA developed the current warnings by designing and testing potential images, potential text statements, and potential pairings of text statements with images multiple times with different groups of consumers to ensure--and be able to demonstrate--that they are unambiguous and unlikely to be misinterpreted or misunderstood (in contrast to *Reynolds'* concern that consumers might misunderstand the image of a man smoking through his tracheotomy hole), and that they do convey warning information (in contrast to *Reynolds'* concerns that images of a woman crying, a small child, and a man wearing an "I QUIT" T-shirt provided no information at all).

Some may argue that, because the warnings will promote greater public understanding about the very real, serious, and sometimes deadly outcomes of cigarette smoking, their factually accurate content may evoke subjective, emotional responses from some consumers based on

their personal history and personality characteristics. In general, the possibility that factual content may evoke an emotional reaction does not render the content less factual. In this context, an emotional reaction on the part of some individuals would not render the warnings or the health information they convey "controversial" or "inflammatory." *CTIA*, 928 F.3d at 847 (holding that sentence of mandated disclosure about cell-phone radiation that "tells consumers what to do in order to avoid exceeding federal guidelines" "may not be reassuring, but it is hardly inflammatory. It provides in summary form information that the FCC has concluded that consumers should know in order to ensure their safety."). There is no controversy about whether cigarette smoking causes the negative health consequences that form the content of the warnings. As discussed more fully in sections VI and VII, the evidence is clear that it does.

FDA also disagrees with comments that the warnings constitute a "mini-billboard" conveying an anti-smoking position on the part of the Government. FDA expresses no such viewpoint through these required health and safety disclosures: there is no "provocatively-named" "1-800-QUIT-NOW" hotline, and no man wearing a T-shirt emblazoned with "I QUIT." Even though not implicated by the final warnings here, FDA disagrees with the suggestion that mandatory cessation messages, such as the current Surgeon General's warning dating to 1984, "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health, Birth, And Low Birth Weight," are ineligible for First Amendment review under *Zauderer*. Cessation statements, like the Surgeon General's warning just quoted, that contain factual and uncontroversial information are appropriately reviewed under the *Zauderer* standard just like other factual disclosures.

FDA also disagrees that its research studies confirm the warnings are not factual. Rather, through the Agency's science-based, iterative research process, FDA designed warnings that are

factually accurate, have concordant textual statements and accompanying images depicting the specific health conditions, and are presented in a realistic and objective format. All warnings (new cigarette health warnings and the current Surgeon General's warnings, which served as the control condition) were perceived as being factual by the vast majority of participants in the consumer research studies. Importantly, we note that "perceived factualness" is distinct and different from actual factual accuracy. For example, when individuals are presented with new information, this new information may be viewed with skepticism and perceived as less factual than information that is familiar or well-known. We describe this in detail in section VI. FDA also disagrees with comments suggesting that the images are not factual because they are exaggerated, not typical, and therefore misleading (see section VII for further discussion). FDA disagrees with comments suggesting that its warnings are misleading because they should and do not take into account consumer understanding of either the relative risk of developing certain health conditions from smoking or the absolute risk of developing such conditions (see section VII.A).

c. Unduly burdensome.

(Comment 7) FDA received several comments stating that the required warnings violate the First Amendment because the size and placement requirements unduly burden speech and are broader than reasonably necessary. The comments raise concerns that each package must bear a required warning that will take up the top 50 percent of the package's front and rear panels and that cigarette advertisements must bear required warnings that occupy at least the top 20 percent of the advertisement. The comments note that communications with consumers are already limited due to bans on television and radio advertisements, promotional items, sponsoring

events, and free samples. As alternatives, some comments suggest text-only warnings or public education campaigns.

Other comments say that the required warnings proposed by FDA do not unduly burden protected speech, noting that the size of the warnings on the packages and in advertisements is mandated by the Tobacco Control Act. One comment states there is no evidence that pictorial cigarette warnings covering 50 percent or more of the package have prevented companies from communicating their brand imagery in any of the over 100 countries that have implemented large health warnings. This comment notes that the health warnings provide additional information and do not prevent companies from communicating their promotional information.

(Response 7) FDA does not believe the warnings unduly burden protected speech. As the Sixth Circuit held, the Tobacco Control Act's warning requirement for cigarettes is not unduly burdensome because a manufacturer has ample opportunity to convey other information of its choosing in the remainder of the packaging or advertisement. *Discount Tobacco*, 674 F.3d at 530-31. By statute, the required warnings for cigarette packages must comprise the top 50 percent of the front and rear panels, and for advertisements at least 20 percent of the area at the top of the advertisement. The Sixth Circuit found that "ample evidence support[s] the size requirements for the new warnings" and "that the remaining portions of their packaging" are sufficient for the companies "to place their brand names, logos or other information." *Id.* at 531, 567. See also *Spirit Airlines*, 687 F.3d at 414 (requirement for airlines to make total price the most prominent cost figure does not significantly burden airlines' ability to advertise). FDA also notes that, when the final rule is in effect, the area of cigarette package and advertising space currently devoted to the Surgeon General's warnings will be available for companies.

The Supreme Court's decision in *NIFLA* is not to the contrary. In *NIFLA*, the Court affirmed that, under *Zauderer*, required disclosures must "extend no broader than reasonably necessary." 138 S. Ct. at 2377. This does not mean that a particular disclosure must be the least restrictive means of accomplishing the Government's objective. Here, FDA has concluded that the scientific literature strongly supports that larger warnings, such as those of the size required by Congress in the Tobacco Control Act and now being issued by FDA in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which promotes improved understanding of the specific health consequences that are the subject of those warnings (Refs. 4 and 15). Furthermore, the exact size of the required warnings is not a constitutional issue. In *Burson v. Freeman*, 504 U.S. 191, 208 (1992), the Supreme Court, having determined that some restricted solicitation-free zone around a voting area was necessary to secure the State's compelling interest in fair elections, considered whether a 100-foot restricted zone was permissible or sufficiently tailored. The Court found that, although there were outside limits on how large the restricted zone could be, the difference between 25 and 100 feet was not "of a constitutional dimension." *Id.* at 210-11. Because FDA has shown that the larger warnings at issue are reasonably necessary to achieve the Government's interest in promoting greater public understanding of the risks of smoking, and because manufacturers retain adequate space in which to undertake their preferred speech, the warnings are not unduly burdensome.

(Comment 8) Some comments state that the requirement to place warnings on the top 50 percent of front and rear panels means that all cigarette packages will look alike when placed in display cases which show only the top halves of cigarette packages, and the requirement will thus inhibit manufacturers' abilities to promote their branded products.

(Response 8) As noted elsewhere, and in accordance with the Sixth Circuit decision in *Discount Tobacco*, 674 F.3d at 530-31, 567, FDA has determined that the statutorily-required placement of warnings at the top 50 percent of front and rear panels of cigarette packages, and the top 20 percent of advertisements, leaves sufficient room for manufacturer speech. There is ample room for manufacturers to distinguish their products from other products using the lower half of a cigarette package and the remaining 80 percent of advertisements for brand names, logos, or other information. There is also additional space on the side panels of cigarette packages due to the removal of the Surgeon General's warnings. Although one comment expresses concern that the rule will render cigarette packages indistinguishable from one another because of certain display cases that show only the top portions of cigarette packages, there is no requirement that display cases be configured that way. Moreover, FDA observes that cigarette display fixtures and cases generally do not display only cigarette package facings, but commonly feature a large amount of "header," "flipper," and other cigarette advertising that is subject only to a 20 percent requirement. The requirements here are distinct from the disclosure requirements found unconstitutional in *NIFLA*, which mandated that the required statement be provided in up to 13 languages, thereby threatening to "drown out" the speaker's own message. 138 S. Ct. at 2378. Here, any such concern is obviated because manufacturers retain 50 percent of the front and rear panels of cigarette packages, and 80 percent of advertisements, for their speech.

(Comment 9) One comment on the RIA suggested that the cigarette companies' reduced ability to communicate branding and other messages through their packs may result in lost communication potential.

(Response 9) We also address the same comment in the Final RIA (Ref. 16). The Final RIA includes an estimate of the immediate costs of a requirement for warnings to use 20 percent

of advertising space. But acknowledging that some economic costs may be associated with a mandatory disclosure provides very little information for any First Amendment analysis. The pertinent constitutional question is instead whether the mandatory disclosure is unduly burdensome and chills protected commercial speech, or whether manufacturers retain adequate space for their speech. *See Zauderer*, 471 U.S. at 651; *see also id.* at 653 n.15 (finding that "[t]his case does not provide any factual basis for finding Ohio's disclosure requirements are unduly burdensome"); *cf. id.* at 663 (Brennan, J., joined by Marshall, J., concurring in part, concurring in the judgment in part, and dissenting in part) (concluding that the majority implicitly acknowledged that a mandatory disclosure, pages long, of "detailed fee information that would fill far more space than the advertisement itself, would chill the publication of protected commercial speech"). As discussed elsewhere in this rule, FDA concludes that the remaining 80 percent of advertisements, and the remaining 50 percent of the principal panel of cigarette packages, provide adequate space for manufacturers' branding and messaging.

3. *Central Hudson* and Strict Scrutiny

(Comment 10) FDA received other comments suggesting that the required warnings are impermissible speaker-, content-, and viewpoint-based regulations of speech. These comments assert that the required warnings FDA proposed would fail under intermediate (*Central Hudson*) scrutiny because FDA has not shown that the warnings would materially and directly advance the substantial Government interest of promoting greater public understanding of the negative health consequences of smoking. The comments suggest that the problem the Government seeks to address is not real because smokers are already aware of the risks of cigarette smoking. Some comments add that even if the focus is on less-known risks, FDA has not shown that promoting greater public understanding of these risks is a substantial interest. Comments further assert that

there would be more narrowly tailored means of addressing those less-known risks, for example, through public health campaigns. Conversely, other comments state that the proposed rule would be constitutional under intermediate scrutiny because FDA has a substantial interest in ensuring that consumers have accurate, factual information about the serious health effects of using products that are offered to them and these required warnings would directly advance that interest, as shown by FDA's quantitative consumer research (Refs. 12 and 17). Finally, at least one comment suggests the warnings are subject to strict scrutiny and cannot survive that standard.

(Response 10) FDA has determined that the warnings also would be constitutional if reviewed under intermediate scrutiny. Under the test for restrictions on commercial speech articulated in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980), agencies can regulate commercial speech where the regulation directly advances a substantial Government interest and is not more extensive than necessary to serve that interest. *Central Hudson* does not require that the means chosen by the Government be the least restrictive means available for addressing an issue, see *Boards of Trustees v. Fox*, 492 U.S. 469, 480 (1989), but the Supreme Court has in any event observed that required factual disclosures are less intrusive from a First Amendment perspective than are restrictions on speech. *Zauderer*, 471 U.S. at 651. Because the Government's interest in these warnings is substantial and the regulation is no more extensive than necessary to directly advance that interest, the rule withstands review even under *Central Hudson*.

As outlined in the preceding paragraphs of this section of the preamble, the risks associated with cigarette smoking present a significant public health problem, and the Government's interest in promoting greater public understanding of those risks is substantial. The

scientific evidence produced by FDA's quantitative consumer research demonstrates that the required warnings in this rule directly advance the Government's interest by outperforming the current Surgeon General's warnings in actually providing "new information" and "self-reported learning," which promote better understanding by the public about the negative health consequences of smoking, among other measured outcomes. As discussed elsewhere, the warnings are no more extensive than necessary to achieve the Government's interest--they provide factual and accurate representations of the dangers of cigarette smoking and apply to all cigarette packages and advertisements by all manufacturers, distributors, and retailers, so they are not over- or underinclusive in scope, and there is enough room remaining on the rest of the packages and advertisements for manufacturers to convey their messages.

Although some comments assert correctly that public health campaigns can be effective in helping raise general awareness of the health risks of using tobacco products, such campaigns may supplement but are not an adequate alternative to placing warnings directly on cigarette packages and advertisements for purposes of advancing the Government's interest. Congress has long required that cigarette warnings appear on packages and in advertisements. As far back as 1965, the FCLAA set forth the policy of a comprehensive warning program on cigarette packages and advertisements so that "the public may be adequately informed" about the dangers of cigarette smoking. FCLAA Section 2(1), codified at 15 U.S.C. 1331(1). This reflects the recognition that, while voluntary public education campaigns can provide effective targeting and messaging, they do not reach every person who looks at a package of cigarettes or advertisements and do not receive as many impressions as a comprehensive program of cigarette package and cigarette advertisement warnings. Studies demonstrate that pictorial cigarette warnings placed directly on products convey the risks to those who look at packages and

advertisements with more immediacy and noticeability (see section VI.B for further discussion). Therefore, FDA disagrees that public education campaigns are adequate alternatives for warnings on packages and advertisements.

Regarding the proposed alternative of text-only warnings, the scientific literature strongly supports that pictorial cigarette warnings promote greater public understanding about the health consequences of smoking as, for example, they: (1) increase the noticeability of the warning's messages; (2) increase knowledge and learning of the negative health consequences of smoking; and (3) benefit subpopulations that have disparities in knowledge about the negative health consequences of smoking (see section V.B of the proposed rule, 84 FR at 42762-65). When Congress amended the FCLAA with the Tobacco Control Act, it recognized that the current 1984 Surgeon General's text-only warnings had become "ineffective in providing adequate warnings about the dangers of tobacco products" (Ref. 14 at 4). To that end, Congress directed new cigarette warnings to be accompanied by color graphics. FDA's quantitative consumer research studies show that the new required warnings with color graphics promote greater understanding of the negative health consequences of smoking than the current 1984 Surgeon General's warnings, which served as the control condition. Each of the final required warnings outperformed the Surgeon General's warnings on the two outcomes FDA specified (as described in section VI.E of the proposed rule, 84 FR at 42771-72) as being predictive for promoting understanding of the risks associated with cigarette smoking: "new information" and "self-reported learning." In addition, the final required warnings also demonstrated statistically significant greater scores in nearly all other measures of understanding when compared to the Surgeon General's warnings (see section VII.B below for a discussion of the study results for each required warning). There is ample scientific evidence that textual warnings accompanied by

large color images will directly advance greater public understanding of the negative health consequences of smoking.

We disagree with the comment that suggests that the required warnings are compelled speech that would be subject to strict scrutiny as content-based regulation of commercial speech, citing *Reed v. Town of Gilbert*, 135 S.Ct. 2218, 2226 (2015), *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), and *NIFLA*. The rule is properly reviewed under *Zauderer* but would also easily survive scrutiny under *Central Hudson*.

In *Reed v. Town of Gilbert*, the Court applied strict scrutiny to content-based restrictions on non-commercial speech in public fora. *Reed* had nothing to do with commercial speech doctrines, much less with the type of disclosure required by this final rule, and it has not been understood to alter the applicability of *Central Hudson* or *Zauderer*. Likewise, *Sorrell* "did not mark a fundamental departure from *Central Hudson*'s four-factor test, and *Central Hudson* continues to apply" to regulations of commercial speech, regardless of whether they are content based. *Retail Digital Network, LLC v. Prieto*, 861 F.3d 839, 846 (9th Cir. 2017) (en banc); accord *Missouri Broad. Ass'n v. Lacy*, 846 F.3d 295, 300 n.5 (8th Cir. 2017). The Supreme Court has never applied strict scrutiny to regulations of this type, notwithstanding that they generally apply only to a specific type of commercial activity, and may thus concern a particular subject. To the contrary, in *NIFLA*, which post-dates both *Reed* and *Sorrell*, the Court reaffirmed that it did "not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *NIFLA*, 138 S. Ct. at 2376.

4. Constitutionality of Statutory Requirement

(Comment 11) Several comments argue that the statutory requirement for "graphic" health warning labels in the Tobacco Control Act itself violates the First Amendment. Other comments express strong support for the cigarette health warning label requirement in the Tobacco Control Act, noting that this provision of the Tobacco Control Act was upheld in *Discount Tobacco*, 674 F.3d 509 (6th Cir. 2012).

(Response 11) Comments addressed to the facial constitutionality of a statute are generally outside the scope of an agency's rulemaking authority. *Am. Meat Inst.*, 760 F.3d at 25 ("We do not think the constitutionality of a statute should bobble up and down at an administration's discretion."). The statutory requirement for cigarette health warning labels was in any event considered in a facial challenge and upheld by the Sixth Circuit in *Discount Tobacco City*, and the Supreme Court denied the manufacturers' petition for a writ of certiorari (569 U.S. 946 (2013)). For the reasons stated in that opinion, and for the additional reasons stated in the preceding paragraphs of this section of the preamble explaining why the final rule is constitutional, the statutory "graphic label statement" requirement is consistent with the First Amendment.

D. Comments Regarding the Administrative Procedure Act (APA)

FDA received comments on a range of APA issues, including general objections that the rule is not the result of deliberative and reasoned decision making and comments that assert FDA failed to support the Agency's findings, ignored alternative evidence, and failed to provide an opportunity to meaningfully comment. Several comments generally note that under the APA courts will set aside a rule if the rule exceeds the Agency's authority, fails to comply with statutory requirements or consider alternatives, or if the action is otherwise arbitrary, capricious,

or an abuse of discretion. As discussed in detail in the following paragraphs, FDA has carefully considered and responded to the APA issues raised in the comments.

1. Adequacy of the Evidence in Support of the Rule

(Comment 12) Several comments assert that the proposed rule violated the APA because under the APA, FDA must engage in "reasoned decision-making" and FDA violated the APA by failing to develop affirmative "substantial evidence" to support the rule or, alternatively, because FDA relied on evidence that does not support the rule. Some comments suggest that FDA violated the APA by not developing a record to support the rule but instead issued the rule based on "speculation, conjecture, or supposition" and that FDA based the proposed rule either on: "(1) a hypothetical reduction in smoking not supported by the record, or (2) a hypothetical problem, lack of consumer awareness of the harms of smoking."

More specifically, some comments argue that FDA has failed under the APA to articulate a rational explanation for the required warnings included in the proposed rule. Comments said that if FDA's interest is consumer awareness, then consumers do not need to be informed of the risks of smoking because there is ample evidence that consumers are well aware of the health risks of cigarette smoking. Other comments argue that FDA's research is flawed as it is inherently biased and fails to account for potential confounding variables and did not reliably test "whether study participants actually learn anything new." With respect to FDA's final quantitative consumer research study, some comments suggest FDA also failed to test whether the proposed images add any new information above and beyond the new text and failed to control for the effect of altering the warnings' size and location. Another comment objects to the final quantitative study as flawed because FDA failed to incorporate the commenter's suggestions on demographic and other factors. Some comments state that both quantitative

studies are also flawed as they did not test comprehension or understanding of the revised textual statements or images and because they enrolled non-representative participants. These comments also argue that FDA's quantitative studies fail to support the proposed required warnings because the study results demonstrate low or no impact of several tested statements or statement-and-image pairings. Other comments suggest that FDA inappropriately relied on non-U.S. studies and on other studies that have design or execution limitations, including lack of comparative effectiveness data, no measurement of understanding, and no evaluation of whether the image contributes to understanding over and above text.

Other comments suggest that if the rule is based on an interest in a reduction in smoking, then FDA has provided no evidence, including no consumer perception and actual use data, that the proposed required warnings would decrease smoking initiation and increase smoking cessation.

(Response 12) FDA disagrees with comments suggesting that the rationale for and evidentiary basis supporting this rule are inadequate. Rather, FDA has both documented the need for this rule and developed a robust record supporting it. As the record demonstrates, the final cigarette health warnings will promote greater public understanding of the negative health consequences of smoking.

The rationale for the rule is clear. Cigarette smoking remains the leading cause of preventable disease and death in the United States, yet the public continues to hold misperceptions about the health risks of smoking and is largely unaware of certain conditions caused by smoking (see section V for further discussion). We disagree with comments that argue the public's knowledge of the general harms of cigarette smoking undercuts the need for these required warnings. Contrary to some comments' discussion of the PATH data, there remain large

gaps in knowledge about the health effects of smoking, with many smokers having little awareness of the wide variety of diseases causally linked to smoking (see section V.B for further discussion). As discussed in more detail in the First Amendment section, the Sixth Circuit concluded that "[t]here can be no doubt that the government has a significant interest in . . . warning the general public about the harms associated with the use of tobacco products." *Discount Tobacco*, 674 F.3d 509, 519 (6th Cir. 2012).

FDA also disagrees that the Agency's research fails to support this rule or that different warning elements should have been tested. FDA undertook a rigorous science-based, iterative research process to develop and test cigarette health warnings depicting the negative health consequences of smoking. FDA's process involved carefully reviewing the scientific literature on the health risks associated with cigarette smoking, evaluating the public's general awareness and knowledge of those health risks, and assessing the Agency's own consumer research on potential revised warning statements (see section VI for further discussion). The Agency's findings as a result of this process showed that the selected pairings of text and pictorial warnings would promote greater public understanding of the negative health consequences of cigarette smoking. FDA further disagrees with comments suggesting that FDA's reliance on other studies in developing its warnings is inappropriate (see section V.B.2 for further discussion).

Accordingly, the proposed rule is justified by the Government's interest in promoting greater public understanding of the negative health consequences of smoking. To the extent some comments suggest that FDA did not prove that the warnings will lead to increased smoking cessation or decreased initiation, FDA notes that increased smoking cessation and decreased initiation are not the purpose of this rule.

(Comment 13) One comment states there is no evidence to support FDA's proposal to include two different images with the textual warning statement of "WARNING: Smoking causes COPD, a lung disease that can be fatal."

(Response 13) FDA is finalizing only one text-and-image pairing for the textual warning statement, "WARNING: Smoking causes COPD, a lung disease that can be fatal."

2. Consideration of Contrary Scientific Evidence

(Comment 14) Some comments suggest that FDA did not adequately consider contrary scientific evidence that undermines the proposed rule, including evidence showing that graphic warnings are ineffective in improving consumer comprehension; evidence showing "shocking images" to be less effective; evidence showing that gruesome images can be seen as exaggerating risks and thus ignored; evidence showing that "fear-based" messages can be ignored or perceived in a defensive manner; or evidence showing that consumers already understand the health consequences of smoking. Comments assert that FDA did not address evidence indicating that the statutory size requirements for warnings on packages and advertisements do not advance consumer understanding.

(Response 14) FDA disagrees with comments suggesting FDA did not adequately consider contrary scientific evidence. As discussed in greater detail below, FDA concludes that those studies with findings contrary to FDA's conclusion regarding images promoting greater understanding may be partly or fully attributable to the fact that the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies (see section V.B.2 for further discussion). With respect to the evidence about the size of the warnings, the proposed required warnings were tested in the sizes specified by section 4 of the FCLAA. The data generated from FDA's final quantitative consumer research

study demonstrate that the 11 final required warnings increase understanding of the negative health consequences of cigarette smoking.

3. Consideration of Alternatives

(Comment 15) Comments state that FDA did not adequately evaluate alternatives to the proposed rule, such as refreshing the Surgeon General's warnings or requiring new, text-only warnings. Other comments suggest that FDA should evaluate the alternatives of smaller or differently placed warnings, or the use of "enhanced public education campaigns."

(Response 15) FDA disagrees with comments suggesting that its consideration of alternatives was inadequate. FDA considered many approaches, including text-only warnings or different graphic approaches, throughout its process. Ultimately, FDA was guided both by Congress's directive to issue regulations with color graphics to accompany new textual warnings and, as described more fully in section VI of the proposed rule, by findings from health communication science research regarding best practices for communicating health risk information to the lay public.

In amending the FCLAA with the Tobacco Control Act, Congress explicitly recognized that the Surgeon General's text-only warnings had become "ineffective in providing adequate warnings about the dangers of tobacco products" (Ref. 14 at 4). To that end, Congress mandated new cigarette textual warning statements to be accompanied by color graphics. Given this directive, testing text-only warnings would not have been an optimal use of FDA's resources. FDA did, however, consider the substantial body of scientific evidence showing that cigarette textual warning statements better promote public understanding of health risks when accompanied by color graphics. Furthermore, as discussed in section VI, FDA's research studies show that the new warnings with accompanying color graphics promote greater understanding of

the risks of smoking than the controls consisting of the (text-only) Surgeon General's warnings (see, also, section V of the proposed rule for a discussion of the literature on the benefits of large pictorial cigarette health warnings).

With regard to comments suggesting that FDA should have considered smaller or differently placed warnings, FDA disagrees. The statute sets forth the requirements with regard to size and placement of the warnings, and the scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which leads to improved understanding of the specific health consequences that are the subject of those warnings (Refs. 4 and 15). The placement of the warnings at the top 50 percent of the front and rear panels of the packages and at least the top 20 percent of advertisements will better ensure noticeability of the warnings. Moreover, the Supreme Court has recognized that decisions with respect to the constitutionality of a regulation do not include second-guessing the details of such regulations. In *Burson v. Freeman*, 504 U.S. at 210-11, the Court, having determined that some restricted zone around a voting area was necessary to secure the State's compelling interest, recognized that the exact size of that space was not a constitutional question. Rather, the constitutional question lies in the outer bounds of a regulation; various permutations within those bounds is a matter for legislators.

FDA also disagrees with comments that FDA should have pursued enhanced public education efforts rather than issuing new warnings. As discussed more fully in the First Amendment section, while public health campaigns can allow for effective targeting and messaging, they do not reach every person who looks at a package of cigarettes or advertisements and do not receive as many impressions as a comprehensive program of cigarette

package and cigarette advertisement warnings. Studies demonstrate that pictorial cigarette warnings placed directly on products convey the risks with more immediacy and noticeability (see section VI.B for further discussion). Accordingly, new warnings with color graphics for packages and advertisements will promote greater public understanding of the risks of smoking.

4. Meaningful Opportunity to Comment

(Comment 16) FDA received comments asserting that the Agency failed to provide an opportunity to meaningfully comment under the APA because FDA did not fully disclose the data, methodologies, summaries, and conclusions relied on to support the proposed rule. Some comments argue that 60 days is not enough time to comment given the complexity of the proposed rule and does not provide the public sufficient time to develop alternative warnings, and one comment requests an extension of the comment period. The comments note that FDA spent years developing the proposed rule and emphasized throughout the proposed rule the complex process the Agency undertook to develop the required warnings. Some comments suggest FDA made errors due to a court order which, they contend, forced the Agency to rush through the final stages of rulemaking or that FDA did not provide sufficient time because the Agency does not intend to consider alternatives. One comment requests a response to a Freedom of Information Act request as essential to being able to meaningfully respond to comments.

(Response 16) We disagree with these comments. Although the Agency is under a court order to send the final rule to the Office of the Federal Register by a specific date, FDA provided a standard 60-day comment period for the proposed rule and the Agency has thoroughly reviewed and responded to all public comments and made changes that are reflected in the final rule based on public input. While the Agency supplemented the docket with requested background information (84 FR 60966, November 12, 2019), as discussed below these

qualitative studies are not key data relied upon by the Agency to make final decisions about the proposed and final rules.

As explained in section VI of the proposed rule, FDA conducted various qualitative focus groups and interviews ("qualitative studies") to test and refine image concepts for the required warnings and to obtain feedback on which textual statements should be selected for further study. In general, qualitative research is used to understand how a research topic is experienced from the perspective of the study participants. It is typically conducted via indepth interviews, participant observation, or focus groups to obtain information about the attitudes, opinions, and behavior of particular populations. FDA did not include the qualitative study reports in the docket as the rulemaking itself did not directly rely upon them. However, because the qualitative studies did inform further FDA research and development, namely, the quantitative consumer research studies, FDA subsequently added these materials to the docket and reopened the comment period for 15 days to allow public input on the supplemental materials (84 FR 60966).

The APA does not include a specific procedural requirement for the length of time an agency must allow for comments. *See Phillips Petroleum Co. v. EPA*, 803 F.2d 545, 559 (10th Cir. 1986) (stating "[t]his opportunity to participate is all that the APA requires"). FDA's regulations generally require that the Agency provide 60 days for comment on proposed regulations (21 CFR 10.40(b)(2)). The Commissioner may shorten or lengthen that time period for "good cause," but in no event is the time for comment to be less than 10 days. *Id.* While FDA regulations permit an extension of comment periods, § 10.40(b)(3)(i), a request to do so "must discuss the reason comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment." *Id.* When agencies have been challenged on

abbreviated comment periods, courts generally look to whether shorter time frames were necessitated by deadlines for Agency action. *See, e.g., Omnipoint Corp. v. FCC*, 78 F.3d 620, 629-630 (D.C. Cir. 1996) (rejecting a challenge to a 15-day comment period given a "congressional mandate [to act] without administrative or judicial delays") (internal quotations and citation omitted); *Fla. Power & Light Co. v. United States*, 846 F.2d 765, 772 (D.C. Cir. 1987) (determining that a 15-day comment period did not violate the APA where the Nuclear Regulatory Commission was under a Congressionally imposed deadline). Courts considering whether a public comment period was long enough also look in particular to whether there is evidence that interested parties did in fact submit meaningful comments. *See, e.g., Fla. Power & Light*, 846 F.2d at 772 (finding "no evidence that petitioners were harmed by the short comment period," where the Commission "received sixty-one comments, some of them lengthy, addressing its proposed rule" and "[t]hose comments had a measurable effect on the final rule") *Conference of State Bank Sup'rs v. Office of Thrift Supervision*, 792 F. Supp. 837, 844 (D.D.C. 1992) (rejecting argument that 30-day comment period was inadequate, "especially in light of the comments that [aggrieved plaintiffs] and other interested parties submitted in response to this proposed rule") (citing 12 pages of comments in administrative record).

Here, the Agency received numerous meaningful comments both in support of and disagreeing with the proposed rule, totaling thousands of pages. The Agency has not only taken those public comments into consideration in issuing this final rule, but also made changes to the final requirements based on that public feedback, including allowing cigarette manufacturers to use different required warnings on the front and rear panels of a cigarette package, and altering the image of the underweight baby on a scale to improve image clarity. The initial 60-day period and supplemental 15-day period for public comment on the notice of proposed rulemaking

provided ample opportunity for public participation in this rulemaking process, and comments have failed to establish a basis under § 10.40(b)(3)(i) for any further extensions of time.

5. Requirement of Random and Equal Distribution

(Comment 17) Comments assert that the random and equal distribution requirement for cigarette packages as applied to the proposed 13 warnings is arbitrary and capricious under the APA because compliance is impossible from a printing perspective. Comments urge that FDA must reduce the number of warnings and provide greater flexibility. These comments suggest FDA misunderstands the printing processes in the United States and that industry cannot comply, particularly in the time allotted. The comments explain the printing process and describe why requiring the random and equal distribution of thirteen warnings is "infeasible."

(Response 17) FDA is finalizing a set of 11 required warnings. FDA disagrees that the statute's and the final rule's requirement for random and equal display and distribution of cigarette package warnings violates the APA. A standardized number of warnings--11 in this final rule, reduced from 13 in the proposed rule--gives the industry a known quantity to implement, and the statute and final rule provides for a 15-month period in which to adjust any printing processes that may require updating. In addition, as we discuss in our responses to the comments that describe implementation concerns (see section X), in preparation for submission of a cigarette plan, FDA encourages manufacturers to engage with FDA sooner rather than later on specific issues related to their product (see also section IX.B.4.e).

V. Need for Rule and FDA Responses to Comments

A. Cigarette Use in the United States and the Resulting Health Consequences

1. Smoking Prevalence and Initiation in the United States

In explaining the need for the proposed rule, we provided information on smoking prevalence and initiation rates among adults and children in the United States. As stated in the proposed rule, cigarettes remain the most commonly used tobacco product in the United States among adults, and a substantial percentage of U.S. adults are cigarette smokers (Ref. 18). Although cigarette smoking prevalence has generally declined over the past several decades, approximately 34.2 million U.S. adults smoke cigarettes, and, among these adult smokers, the vast majority--74.6 percent, or approximately 25.5 million people--smoke every day. Smoking prevalence remains higher than the national average among certain demographic subgroups of the adult population. For example, among adults with differing levels of education, the highest prevalence rates have been observed in adults with lower education levels. Data indicate that 36.0 percent of adults with a General Education Development certificate and 21.8 percent of adults with less than a high school diploma were current smokers in 2018, compared with 7.1 percent of adults with a college degree and 3.7 percent of adults with a graduate degree (Ref. 19).

Despite recent declines in youth smoking rates, the 2019 National Youth Tobacco Survey data showed that past 30-day smoking prevalence among high school students was 5.8 percent, representing 860,000 youth, of which 32.5 percent were frequent smokers (defined as cigarette use on 20 or more of the past 30 days) (Refs. 20 and 21). The data also showed that past 30-day prevalence among middle school students was 2.3 percent, representing 270,000 youth (Ref. 20). Results from the 2018 National Survey on Drug Use and Health demonstrate that, on average, each day in the United States, approximately 1,600 youth ages 12 to 17 smoke their first cigarette, and 170 youth ages 12 to 17 become daily cigarette smokers (Ref. 22 at Table A.3A).

2. Negative Health Consequences of Smoking

As described in the proposed rule, the health risks associated with cigarette smoking are significant. Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year among cigarette smokers and those exposed to secondhand smoke (Ref. 3). Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Refs. 23 and 24). Over 16 million Americans alive today live with disease caused by smoking cigarettes (Ref. 3).

Since the first Surgeon General's Report published in 1964, evidence of the negative health consequences of cigarette smoking and secondhand smoke has expanded dramatically. For example, the 2014 Surgeon General's Report (Ref. 3) presented a robust body of scientific evidence documenting the health consequences from both smoking and exposure to secondhand smoke across a range of diseases and organ systems. In particular, the 2014 Surgeon General's Report added eleven diseases to the long list of diseases causally linked to cigarette smoking: liver cancer, colorectal cancer, age-related macular degeneration, orofacial clefts in newborns from maternal smoking during pregnancy, tuberculosis, stroke (for adults), diabetes, erectile dysfunction, ectopic pregnancy, rheumatoid arthritis, and impaired immune function (Ref. 3 at pp. 4-5). The health conditions established to be causally linked to cigarette smoking in the 2014 Surgeon General's Report are in addition to the more than 40 unique health consequences of cigarette smoking and exposure to secondhand smoke determined by earlier studies (Ref. 3).

FDA received many comments that were strongly supportive of the proposed rule, many of which reiterate the negative health consequences of cigarette smoking described in the proposed rule and stressed the need for public health measures, such as new cigarette health

warnings, to communicate the latest science to the public. FDA did not receive comments disputing that cigarette smoking is harmful to human health.

(Comment 18) Several comments emphasize that, given the substantial health toll of tobacco use, "it is difficult to imagine a more compelling governmental interest than to ensure that the public understands the health consequences of smoking" and that health warnings on cigarettes are one of the most efficient and effective ways of doing so.

(Response 18) FDA agrees that the health toll from cigarettes is substantial and that the required warnings in the final rule will improve public understanding about the breadth of negative health consequences caused by smoking. As explained in section V.B of the proposed rule, the scientific literature demonstrates that cigarette health warnings that are noticeable, lead to learning, and increase knowledge will promote greater public understanding of the negative health consequences of smoking, and FDA's consumer research has demonstrated that the required warnings will advance this important governmental interest.

(Comment 19) A comment (from a public health group and a network of state and territorial tobacco prevention and control programs across the United States) expressed support for FDA to fully implement all of the warnings in the proposed rule. The comment states the rule is complementary to the needs and goals of public health agencies and that the required warnings on cigarette packs and advertisements will effectively and appropriately support state and territory-based efforts to educate smoking and nonsmoking consumers.

(Response 19) FDA agrees that the final rule will complement other educational efforts that inform smokers and nonsmokers about the negative health consequences of smoking. As we discuss in section VII, following consideration of the public comments received in the docket, as well as based on the results of our consumer research studies, existing scientific literature on

cigarette health warnings, and legal and policy considerations, FDA is finalizing 11 of the 13 required warnings.

(Comment 20) Some comments provide additional information that smoking disproportionately harms (through both higher prevalence and tobacco-related death and disease) many marginalized populations, including African-Americans; American Indians, and Alaskan Natives; people with low incomes, low educational attainment, and low health literacy; people who identify as lesbian, gay, bisexual, or transgender; and people with behavioral health and substance use conditions (see, e.g., Refs. 25–28).

(Response 20) FDA agrees that cigarette smoking disparities exist among specific subpopulations in the United States. As described in section IV.A of the proposed rule, smoking prevalence is higher in some subpopulations (e.g., those with lower socioeconomic status (SES)) than the general U.S. population (Refs. 18, 29, and 30). For the reasons explained in section V.B.2 of the proposed rule, some subpopulations experience disparities in knowledge of the health harms of smoking due to lower health information access and lower health literacy, and the evidence collectively demonstrates that pictorial cigarette warnings, such as the required warnings being issued in this final rule, are effective across diverse populations and settings and will likely help reduce disparities found in consumer understanding about the harms of smoking.

B. Data Concerning Cigarette Health Warnings

1. The Current 1984 Surgeon General's Warnings Are Inadequate

In the preamble to the proposed rule, FDA observed that cigarette packages and advertisements can serve as important channels for communicating health information to broad audiences that include both smokers and nonsmokers. Daily smokers are potentially exposed to the warnings on packages over 5,100 times per year, and, because these packages are not always

concealed and are often visible to those other than the person carrying the package, including retail customers, warnings on those packages are potentially viewed by many others, including nonsmokers (Refs. 31 and 32). Smokers and nonsmokers, including adolescents, also are frequently exposed to cigarette advertising appearing in a range of marketing channels, including print and digital media, outdoor locations, and in and around retail establishments where tobacco products are sold (Refs. 33 and 34). The inclusion of health warnings on cigarette packages and in advertisements therefore can provide a critical opportunity to help smokers and nonsmokers of all ages better understand the negative health consequences of smoking. However, the current 1984 Surgeon General's warnings have suffered from three critical problems: (1) they have not changed in more than 35 years and long ago became effectively stale; (2) they do not effectively promote greater public understanding of the risks of smoking because they do not attract attention, are not remembered, and do not prompt thoughts about the risks of smoking; and (3) they do not address areas where there are significant gaps in public understanding about the negative health consequences of cigarette smoking (see section V.A of the proposed rule).

The proposed rule presented extensive evidence from the scientific literature regarding how the current 1984 Surgeon General's warnings are largely unnoticed and unconsidered by both smokers and nonsmokers (see section V.A.2 of the proposed rule). FDA also provided clear evidence that consumers suffer from a pervasive lack of knowledge about and understanding of many of the negative health consequences of smoking and the current Surgeon General's warnings are inadequate to address these knowledge gaps.

We received numerous comments supporting our analysis regarding the inadequacy of the current 1984 Surgeon General's warnings that appear on cigarette packages and in cigarette advertisements. FDA also received many comments regarding the level of consumers'

knowledge and understanding of the health risks of smoking. Several comments stated that the public is adequately informed about the risks of smoking, while many other comments explained that consumers lack knowledge about a wide variety of smoking risks. These comments, and our responses, are summarized below.

(Comment 21) A substantial number of comments strongly support the proposed rule and urge FDA to include all 13 proposed required warnings in the final rule. These comments cite as support: the more than 35 years since the current 1984 Surgeon General's warning labels were changed; the conclusion that the current Surgeon General's warnings are "wholly inadequate" because they are not noticed and fail to address many of the health harms of smoking of which the public has little knowledge; the demonstrated gaps in public awareness and knowledge of the health risks of tobacco use; the well-established and "overwhelming" findings that large pictorial cigarette warnings such as those included in the proposed rule can effectively promote public awareness and understanding of the negative health consequences of smoking through conveying the risks of smoking and secondhand smoke (Ref. 35); and FDA's scientific evidence and research studies establishing that the proposed warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

(Response 21) FDA agrees that there is a strong need for new cigarette health warnings because, as noted in section V.A of the proposed rule, the current 1984 Surgeon General's warnings are inadequate because they do not attract attention, are not noticed, do not prompt consumers to think about the risks of smoking, are not remembered, do not address the breadth of negative health consequences of smoking, and have not been updated in more than 35 years. FDA agrees that large pictorial cigarette warnings, such as the ones required in the final rule, will

address the noted issues by attracting attention and focusing on less-known health consequences of smoking to promote greater public understanding of the negative health consequences of smoking (see section V.B of the proposed rule and section V.B of the final rule).

(Comment 22) Several comments strongly support FDA's aim in issuing new cigarette health warnings, which is to promote greater public understanding of the negative health consequences of smoking. One comment from an academic researcher states that the proposed warnings' focus on "novel" health effects, for which there are lower levels of public awareness, is an appropriate and effective strategy. Comments from multiple professional medical associations emphasize that their medical professional members know first-hand the devastating impact of tobacco-related death and disease on the patients, including children, they treat in their clinical practice every day. Many comments from public health providers and advocacy groups, including those caring for children, strongly encourage FDA to finalize the proposed rule as quickly as possible (no later than the federal court deadline) and to implement the enhanced warning labels without further delay. Another comment, submitted by an academic researcher, emphasizes that the proposed rule presents a "unique opportunity" to educate consumers on some of the less-known health effects of tobacco use, including bladder cancer, erectile dysfunction, and diabetes, stating that "these health effects are among those that consumers and the general public in the U.S. are largely less aware," according to research conducted by the researcher.

(Response 22) As described in the proposed rule, when developing the new cigarette health warnings, FDA consulted the epidemiological literature of causally-linked health conditions as identified in the Surgeon General's Reports and scientific literature (see sections VI.A and VII.A of the proposed rule). FDA developed cigarette health warnings that focus on negative health effects that are less known or less understood by consumers. FDA agrees that the

required warnings, once implemented, will promote greater public understanding of the negative health consequences of smoking.

(Comment 23) A number of comments support FDA's finding that the current 1984 Surgeon General's warnings are inadequate and not taken seriously by consumers, public understanding of the health impacts of smoking is still limited, and large, pictorial cigarette warnings can increase knowledge of the health harms of smoking. Some comments discuss the wide range of studies that indicate that the existing warnings on cigarette packages and in cigarette advertisements are substantially less effective at communicating the health effects of smoking than larger pictorial cigarette warnings and are associated with substantial disparities in health knowledge.

(Response 23) FDA agrees with these supportive comments that the current 1984 Surgeon General's warnings on cigarette packages and in cigarette advertisements are inadequate and ineffective in communicating the health harms of smoking and that the larger pictorial warnings required by this rule will be more effective in helping promote greater public understanding of the negative health consequences of smoking.

(Comment 24) A comment asserts that FDA's proposed rule references some published studies that are older, do not specifically address the current state of the public's knowledge, or focus on smoking-related health effects (e.g., cervical cancer, infertility, kidney cancer, osteoporosis) that are not found in the proposed warnings. The comment states that none of the studies are directly relevant in showing what the U.S. population currently knows about the health risks identified in the proposed required warnings.

(Response 24) To examine public understanding of the negative health consequences of smoking within the U.S. population, FDA conducted qualitative and quantitative consumer

research studies that recruited youth, young adults, older adults, smokers, and nonsmokers in addition to our review of the existing scientific literature. Our findings reinforced what is known about public misperceptions of the health harms of smoking while also addressing gaps that the comment identifies with updated and relevant scientific support.

As discussed in section V.A.3 of the proposed rule, 84 FR at 42761-62, consumers suffer from a pervasive lack of knowledge about and understanding of the many negative health consequences of smoking, and importantly, the published literature indicates that consumers do not understand the wide *range* of illnesses caused by smoking. Due to these gaps in public understanding about the negative health consequences of smoking, as seen in the literature, FDA developed the required warnings to cover a range of smoking-related health effects (as described in section VI of the proposed rule) in order to improve public understanding (see section V.B.2 of the proposed rule, 84 FR at 42763-65 ("Pictorial Cigarette Warnings Can Address Gaps in Public Understanding About the Negative Health Consequences of Smoking")). Additionally, FDA's rigorous science-based, iterative research and development process confirmed that there are substantial consumer knowledge gaps in in the United States and that the required warnings focusing on the specific health consequences highlighted will meet FDA's objectives, especially as indicated by outcomes of "new information" and "self-reported learning" (see section VI of the proposed rule and sections VI and VII of this final rule).

(Comment 25) Several comments discuss the disproportionate burden of smoking observed for some subgroups (e.g., those with lower SES, non-English speakers) and state these subgroups also have disparities in knowledge about the negative harms of smoking. Several comments state that these subgroups tend to have lower levels of health literacy, limited access to information about the hazards of smoking, and tend to benefit the least from textual warnings

on smoking harms. As a result, many comments state that cigarette health warnings with images depicting the harms of smoking will benefit these subgroups by effectively communicating the negative consequences of smoking to diverse populations.

(Response 25) FDA agrees. As discussed in section V.B.2.c of the proposed rule, 84 FR at 42764-65, research shows that pictorial cigarette warnings are effective for diverse populations that differ in cultural, racial, ethnic, and socioeconomic backgrounds. Pictorial cigarette warnings are likely to help reduce disparities among disadvantaged groups in consumer understanding about the harms of smoking.

(Comment 26) Two comments argue that individuals in the United States have substantial exposure to smoking-related information from a wide array of Federal, State, and other public health sources which results in high awareness of the negative health effects of smoking, rendering the proposed cigarette health warnings ineffective in increasing consumer understanding of the negative health consequences of smoking and that FDA has failed to address scientific evidence showing that consumers already understand the health consequences of smoking. In support of that argument, one comment describes survey findings from FDA's PATH, the Gallup Poll, and the National Survey on Drug Use and Health (NSDUH) that show high proportions of respondents indicating awareness that smoking cigarettes is generally harmful to one's health. Additionally, the comment submits an analysis of PATH data from adult respondents that describes perception measures of smoking-related health effects and associations with current smoking status. The comment also cites published studies and draws the conclusions that the U.S. population has high levels of knowledge regarding general and specific smoking-related health effects, the public overestimates the risks of smoking, and the

proposed cigarette health warnings would be ineffective at increasing consumer understanding of the negative consequences of smoking.

(Response 26) FDA disagrees with the view that the public already has a strong understanding of the health consequences of smoking. As discussed in section V.A.3. of the proposed rule, 84 FR at 42761-62, consumers suffer from a pervasive lack of knowledge about and understanding of many of the negative health consequences of smoking (see also section VI.A of the proposed rule, 84 FR at 42766-67, citing research studies finding that consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in current warnings, as well as more specific information about the negative health effects and their mechanisms). Moreover, and importantly, the published scientific literature indicates that consumers do not understand the wide range of illnesses caused by smoking. As discussed in section V.B.2 and VI.D of the proposed rule, 84 FR at 42763-64, 42770, pictorial cigarette warnings have been demonstrated to address these gaps in public understanding about the negative health consequences of smoking by conveying new information in a large and prominent format that will attract attention, be noticed, prompt consumers to think about the risks of smoking, and be remembered.

The data that the comment cites on general awareness of the harms of smoking in FDA's ongoing PATH study, the Gallup Poll, and NSDUH are not relevant to this rulemaking. The goal of the required warnings is not to increase perceptions of general harm of smoking as measured by questions in these surveys, such as "How harmful do you think cigarettes are to health?" or "Do you think smoking is harmful to you?" Rather, the goal is to promote greater public understanding of the negative health consequences of smoking as conveyed in the required

warnings, which address specific health consequences rather than health consequences in the abstract.

The statement also describes an analysis of the publicly available PATH data from Wave 1 (2013-2014), Wave 2 (2014-2015), and Wave 3 (2015-2016). The comment's analysis attempts to examine perception measures of the specific health harms of smoking referenced in the required warnings. We have concerns with the analysis presented in the comment of PATH data for specific health outcomes. Significant limitations include a lack of description of the methods and statistical approach, which make it unclear how perceptions/awareness across the three waves used in the analysis were calculated and whether the longitudinal data were properly weighted. In addition, there is a lack of data from youth (younger than 18), for whom these questions were not assessed, which may potentially bias the results as younger people may be less informed about the range of health consequences caused by smoking.

Beyond concerns with the analytic approach, there are important limitations in the analysis's attempt to extrapolate from PATH survey items to the required warning topics. Many of the items used do not align well with the topic covered in the proposed warnings. For example, the specific smoking-related health effect found in the PATH item "Based on what you know or believe, does smoking cause . . . [h]arm to fetuses (or unborn children) during pregnancy from second-hand smoke?" is purportedly aligned with the statement "WARNING: Smoking during pregnancy stunts fetal growth." Similarly, the specific smoking-related health effect found in the PATH item "Based on what you know or believe, does smoking cause . . . [l]ung disease such as emphysema in smokers?" is purportedly aligned with the textual statement "WARNING: Smoking causes COPD, a lung disease that can be fatal." Although these PATH items may assess general awareness of related health conditions, they do not have sufficient

specificity to draw conclusions about the required warnings and the particular health conditions on which they are focused. Even for items that more directly relate to the textual warning statements such as the one found for bladder cancer ("WARNING: Smoking causes bladder cancer, which can lead to bloody urine"), the PATH item "Based on what you know or believe, does smoking cause . . . [b]ladder cancer in smokers?" does not fully capture all information found in the required warning, such as the symptoms of bladder cancer in this example. More importantly, the PATH items do not capture information that is conveyed in the image depicting the negative health outcome, but rather only focus on one element of the warnings: the textual warning statement.

Even setting all those serious limitations aside, the evidence presented in the comment based on PATH data still show that there are significant opportunities to further promote greater public understanding of the risks associated with cigarette smoking through the required warnings. For example, even according to the comment's own analysis of PATH data, awareness among adults that smoking causes blindness (an incomplete measure of understanding that smoking causes cataracts, which can lead to blindness), was less than 50 percent, and awareness among adults that smoking causes bladder cancer was less than 60 percent. Additionally, simply being aware that smoking causes a specific health condition is not the same as understanding. As described in section V of the proposed rule (see the first paragraph of this response), understanding the negative health harms of smoking is multifaceted and comprises many processes involving attention, reading, knowledge, thinking about the risks, learning, information processing, and recall.

A more appropriate test of understanding that smoking causes the specific health conditions in the required warnings is FDA's final quantitative consumer research study (Ref.

17), which examined those specific outcomes among youth and adults and used study questions that were specific to the warnings being tested. As outlined in section VII, the individual required warnings provided new information to between 35.7 and 88.7 percent of participants in the study, and the required warnings were all perceived to be more helpful in understanding negative health effects than the current 1984 Surgeon General's warnings.

The comment also concludes that the public overestimates the risk of smoking, citing data from an academic researcher (Refs. 36 and 37). However, that research reports on surveys that were paid for and commissioned by tobacco-industry law firms in 1985, 1997, and 1998 for use in defending the tobacco industry against litigation and has been criticized on methodological and other grounds in the public health and psychology scientific literature (Ref. 38; see also, e.g., Refs. 39 and 40).

2. Cigarette Health Warnings That Are Noticeable, Lead to Learning, and Increase Knowledge Will Promote Greater Public Understanding About the Negative Health Consequences of Smoking

The process of getting individuals to understand a message is a multifaceted process, as individuals must first attend to the message (i.e., notice and be made aware of the message), and then they must process the information in the message (i.e., acquire knowledge of and learn that information) (Ref. 41). As FDA discussed in the proposed rule, a large body of scientific evidence demonstrates that large, pictorial cigarette warnings, such as those required in the final rule, promote greater public understanding about the health consequences of smoking as they: (1) increase the noticeability of the warning's message, resulting in increased consumer attention to, reading, and recall of the message; and (2) increase knowledge, learning, information processing of, and thinking about the negative health consequences of smoking. Pictorial

cigarette warnings address gaps in public understanding of the negative health consequences of smoking as the visual depictions of smoking-related disease in the warnings reinforce what is in the text of the warnings while also providing new information beyond what is in the text (Ref. 42; see also Ref. 43). As described in section V.B.2.c of the proposed rule, pictorial cigarette warnings can increase understanding of the negative health consequences of smoking across diverse populations while also benefitting subpopulations that have disparities in knowledge about the negative health consequences of smoking. Given the widespread implementation of large pictorial cigarette warnings on cigarette packages in over 100 countries around the world, real world experience from those countries support these conclusions. FDA received many comments on the effectiveness of large pictorial cigarette warnings in increasing public understanding of the health harms of smoking. Those comments, and FDA's responses, are summarized below.

(Comment 27) Multiple comments agree that the evidence conclusively shows that cigarette health warnings that combine images and text are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking. One comment, citing the 2012 Surgeon General's Report (Ref. 33), states that "health warnings on cigarette packages are a direct, cost-effective means of communicating information on health risks of smoking to consumers" and that such warnings increase knowledge about the harms of tobacco use. One comment notes that the scientific evidence shows that cigarette health warnings increase attention, noticeability, recall, information processing, and understanding of the warnings. The comment also states that visual depictions of smoking-related disease in pictorial cigarette warnings provide new information beyond what is found in the text of the warnings by helping to reinforce and also depict and explain the health effect in the text. The comment cites a

2008 report by the World Health Organization (WHO) (Ref. 44), which concluded that health warnings on tobacco packages increase smokers' awareness of their risk by use of pictures that depict the harms of smoking. Another comment notes that cigarette health warnings that combine images and text increase understanding of the risks of smoking by increasing attention, objective knowledge about risks, self-reported learning, and thinking about the risks of smoking.

(Response 27) FDA agrees that the scientific evidence shows that pictorial cigarette health warnings are more effective than text-only warnings at increasing knowledge and public understanding of the negative health consequences of smoking. As described in section V.B. of the proposed rule, a robust body of scientific literature shows that cigarette health warnings that combine images and text promote public understanding of the negative consequences of smoking. For example, research shows that compared to text-only cigarette warnings, pictorial cigarette warnings are more likely to be noticed (Refs. 45–57); to be read, looked at closely, and recalled (Refs. 48 and 58); to lead to higher knowledge gain and learning (Refs. 59 and 60); and to lead to thinking about the message content (Ref. 61).

(Comment 28) A comment cites a published meta-analysis (Ref. 61) of 37 studies across 16 countries that summarizes much of the current evidence base describing how cigarette health warnings that combine images and text outperform text-only warnings on outcomes such as attracting and holding attention and stronger cognitive reactions such as perceived credibility and thinking about the risks.

(Response 28) FDA appreciates the submission of this important and comprehensive research. This meta-analysis was included in the proposed rule as Ref. 50 and was discussed, along with other supportive information about the ability of pictorial cigarette warnings to improve understanding, in section V.B.2.b of the proposed rule in a subsection entitled "Pictorial

cigarette warnings increase information processing and learning of new information about the negative health consequences of smoking."

(Comment 29) One comment from a large international tobacco research program provides an analysis of natural experiment data collected from 13 countries assessing real-world changes in adult smokers' knowledge of the health conditions--that focus on the same health conditions as those included in the proposed required warnings--before and after implementation of pictorial cigarette warnings in those countries. The comment's analysis indicates that, in all countries, there was generally no change in smokers' knowledge of already well-known health effects following implementation of pictorial cigarette warnings but that pictorial cigarette warnings can lead to further increases in knowledge of health effects for which awareness levels are already quite high. The analysis also indicated that pictorial cigarette warnings significantly improved awareness of less-known health effects and that pictorial cigarette warnings that are large and appeared on both the front and back of cigarette packs were more effective for increasing health knowledge. In addition, the comment estimates that, after the introduction of the proposed warnings in the United States, an additional 3.84 million smokers would know/be aware that smoking causes gangrene, an additional 5.22 million smokers would know/be aware that smoking causes blindness, an additional 3.22 million smokers would know/be aware that smoking causes impotence, and an additional 5.90 million smokers would know/be aware that smoking causes bladder cancer.

(Response 29) FDA appreciates the submission of this analysis of real-world data on the impact of the introduction of pictorial cigarette health warnings on smokers' knowledge of the negative health consequences of smoking. We agree that, once implemented, the required warnings will have a positive impact on the public's understanding of the negative health

consequences of smoking. Indeed, in section V of the proposed rule, we discussed data (see, e.g., Refs. 4, 45, 46, 61, and 62) regarding how cigarette health warnings can inform the public and lead to improvements in health knowledge by, in part, increasing noticeability of the warnings and attention paid to the warnings, and that the current 1984 Surgeon General's warnings are rarely noticed or read.

The results submitted do have some limitations that are common to real-world natural experiments, such as differences in the demographics of smokers between the countries studied and the United States. There are also some differences between the warnings in the countries studied and the final required warnings in the United States in terms of the size of the warnings (ranging between 30 and 90 percent of the pack) and placement of the warnings (i.e., on front and back of packs or just one side). Additionally, the measures used in the comment's submitted study do not match the exact wording or exact health consequences depicted in the proposed required warnings (e.g., secondhand smoke causes asthma in children versus tobacco smoke can harm your children). Finally, this study only includes adult smokers, so it cannot account for the potential improvements in understanding of the negative health consequences of smoking among other nonsmoking adults or among youth.

Although there are limitations to applying evaluation findings from other countries to the United States, the evidence submitted by the comments addresses many of these limitations with its longitudinal cohort design and robust number of countries included in the analysis and as such provides a useful framework to understand the anticipated effect of the required warnings.

(Comment 30) A comment asserts that FDA failed to adequately address contrary evidence indicating that graphic warnings do not meaningfully influence consumer knowledge regarding the health consequences of smoking. The comment states that FDA ignores findings

from U.S.-based studies that demonstrate little or no contribution of added color graphics to textual warning messages (Refs. 63–67).

(Response 30) In section V.B.2.a of the proposed rule, we acknowledge a small number of U.S.-based studies that failed to find that the specific pictorial cigarette warnings tested in those studies had an effect on increasing study participants' agreement with correct health beliefs about the negative effects of smoking. As we discussed in the proposed rule, the failure to find an effect may be partly or fully attributable to the fact that the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies, such as the nine warning statements set forth by Congress in the Tobacco Control Act that focus on better-known health consequences of smoking. Some of the comments cited recently published studies, and we have since completed review of those studies. One study (Ref. 66) compared participants who viewed pictorial cigarette warnings, based on the nine TCA statements, to those who viewed the text-only versions of the warnings. The study found that the pictorial cigarette warnings using the nine TCA statements did not promote greater public understanding when compared to text-only warnings, which is consistent with previous findings (Ref. 68). These findings are also consistent with FDA's first quantitative consumer research study, which showed that, generally, relatively few study participants reported the nine TCA statements to be new information (Ref. 12), and further support FDA's decision to develop and test new textual warning statements beyond the nine statements in the Tobacco Control Act. Finally, the comment cites additional studies that focus on the effect of pictorial cigarette warnings on emotional reactions or behavioral outcomes (e.g., implicit or explicit negative evaluations) (Ref. 67), cigarette purchasing behavior (Ref. 65), quit intentions and quit attempts (Ref. 63), and smoking behaviors (Ref. 64), each of which is beyond the scope of this

rulemaking. The purpose of the final rule is to promote greater public understanding of the negative health consequences of smoking.

(Comment 31) One comment questions FDA's use of existing published scientific studies from outside of the United States, which it considers unreliable scientific evidence to support the rule.

(Response 31) FDA disagrees that published scientific studies from outside the United States are, by definition, unreliable scientific evidence to support the final rule. The consistency of findings on the effectiveness of pictorial cigarette warnings across countries supports both the scientific validity and reliability of the effect of pictorial cigarette warnings, irrespective of country-specific contexts. In section V.B of the proposed rule, FDA discusses studies that demonstrate how pictorial cigarette warnings promote greater understanding about the health consequences of smoking. Some of the cited literature includes studies conducted outside of the United States. These international data are appropriate because they provide empirical support for the role of pictorial cigarette warnings in generally promoting understanding of the negative health consequences of smoking, especially as some of those studies test the effect of the actual implementation of pictorial cigarette warnings at the national level, which is not currently possible to study in the United States. Like those international studies, U.S.-based studies support the conclusion that pictorial cigarette warnings promote greater understanding of the negative health consequences of smoking. Accordingly, this body of scientific literature further confirms the findings from FDA's own consumer research studies demonstrating that the required warnings will promote greater public understanding.

(Comment 32) Some comments mention public education campaigns as an alternative to requiring cigarette manufacturers to display cigarette health warnings on their packaging and in

their advertising. One comment states that FDA did not consider the potential for enhanced public education campaigns as a less burdensome approach to advance its objective and promote consumer understanding. Another comment states that "there is also strong evidence that an FDA-run public-education campaign would be significantly more effective than the proposed graphic warnings" and that such campaigns have several advantages over graphic warnings.

(Response 32) FDA and others have been actively engaged in a variety of public education campaigns related to cigarette and other tobacco product use, and these campaigns have made positive contributions to educating the public. However, given the enormity of the public health consequences of cigarette smoking in the United States, and the large and diverse sectors of society affected by cigarette smoking, Congress correctly concluded that this channel for communications was not by itself sufficient. Accordingly, in enacting the Tobacco Control Act, Congress amended section 4 of the FCLAA and directed FDA to issue new cigarette health warnings that include color graphics depicting the negative health consequences of smoking to accompany new textual warning statements (section 201 of the Tobacco Control Act, which amends section 4 of the FCLAA). Furthermore, research shows that cigarette packages and advertisements can serve as important channels for communicating health information to broad audiences that include both smokers and nonsmokers (Refs. 43 and 45). Daily smokers, who in 2016 averaged 14.1 cigarettes per day, are potentially exposed to the warnings on packages over 5,100 times per year, and, because these packages are often visible to individuals other than the person carrying the package, warnings on those packages are potentially viewed by many others, including nonsmokers (Refs. 43 and 69). Also, smokers and nonsmokers, including adolescents, are frequently exposed to cigarette advertising appearing in a range of marketing channels, including print and digital media, outdoor locations, and in and around retail establishments

where tobacco products are sold. FDA agrees that there is an important role for other educational efforts to inform smokers and nonsmokers about the negative health consequences of smoking; however, while such efforts complement the required warnings, they are not, by themselves, an effective alternative.

VI. FDA's Approach to Developing and Testing Cigarette Health Warnings Depicting the Negative Health Consequences of Smoking

As explained in the proposed rule, FDA undertook a rigorous science-based, iterative research process to developing and testing cigarette health warnings depicting the negative health consequences of smoking. FDA's process involved carefully reviewing the scientific literature on the health risks associated with cigarette smoking, evaluating the public's general awareness and knowledge of those health risks, and assessing the Agency's own consumer research on potential revised warning statements. Part of this iterative process included considering whether to revise the nine TCA statements to promote greater public understanding of the risks associated with cigarette smoking. FDA determined there was sufficient support to propose adjusting the text of the TCA statements, as authorized by section 4(d) of the FCLAA (as amended by section 202(b) of the Tobacco Control Act). The process also included undertaking two large consumer research studies, the second of which built on the findings from the first.

The first quantitative study was a large (2,505 participants) consumer research study to assess which, if any, of 15 revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to the 9 TCA statements (OMB control number 0910-0848). In this first quantitative consumer research study, each of the 9 revised textual warning statements that are included in this final rule demonstrated statistically significant higher levels on the two key measures (i.e., "new information" and "self-

reported learning") that are predictive for the task of identifying whether a revised warning statement will promote greater public understanding of the risks associated with cigarette smoking. The second, final quantitative study was a large (9,760 participants) consumer research study to test 16 text-and-image pairings against the current Surgeon General's warnings (OMB control number 0910-0866). We discuss the results of the final consumer research study in this section.

Both quantitative consumer research studies are described in detail in the proposed rule, along with the other steps that informed FDA's selection of the cigarette health warnings. The proposed rule also included as references the draft study reports for each quantitative study, and these reports describe the studies and present the results of the analyses from the studies. At the time the proposed rule published, the reports were undergoing peer review, and these studies have since completed peer review and are available in the docket for this final rule (Refs. 12 and 17).

A. FDA's Final Consumer Research Study Findings

FDA's final large quantitative consumer research study strongly supports the Agency's determination that the final required warnings will promote greater public understanding of the negative health consequences of cigarette smoking. The 11 final required warnings outperformed the current 1984 Surgeon General's warnings on the two outcomes FDA determined are predictive for promoting understanding of the risks associated with cigarette smoking: "new information" and "self-reported learning." In addition, the final required warnings also demonstrated statistically significant improvement in nearly all other measures of understanding when compared to the Surgeon General's warnings.

Prior to conducting the study, FDA's study design specified that, to be considered for regulatory action, individual warnings would have to demonstrate statistically significant improvements, as compared to the current Surgeon General's warnings (which were used as the control condition), on both of two specific outcome measures: "new information" and "self-reported learning" (Ref. 204). The completed research results show that all 11 final required warnings surpassed the Surgeon General's warnings on both of these outcome measures. In addition, as the final study report demonstrates, all 11 of the final required warnings also surpassed the Surgeon General's warnings on six other measures; beyond the "new information" and "self-reported learning" outcome measures, all 11 final required warnings also led to more thinking about risks; were higher on perceived informativeness, perceived understandability, and perceived helpfulness understanding health effects; attracted more attention; and were better recalled (Ref. 17).

1. Study Design

As described in section VI.E of the proposed rule, 84 FR at 42771-72, the purpose of FDA's final quantitative consumer research study (OMB control number 0910-0866) was to assess the extent to which any of the 16 tested cigarette health warnings, developed through FDA's science-based, iterative research process, increase understanding of the negative health consequences of cigarette smoking. More details about the full study results can be found in the final peer-reviewed study report, which we have included in this docket (Ref. 17). Because the purpose of this final quantitative consumer research study was to identify which of the 16 tested cigarette health warnings increase understanding of the negative health consequences of cigarette smoking, the study was not designed to put the tested cigarette health warnings in a rank order or compare individual results of one cigarette health warning to another. FDA evaluated the

research results for each individual tested cigarette health warning to determine which warnings to include in the proposed rule. In doing so, FDA rejected 3 of the 16 warnings that were tested because they did not outperform the current Surgeon General's warnings on both the "new information" and "self-reported learning" outcome measures that FDA determined are predictive of improved understanding. In finalizing the rule, FDA continued to review and evaluate the research results and has narrowed the 13 previously proposed warnings even further, down to the 11 final required warnings. Section VII provides the individual results from the final consumer research study for each of the 11 final required warnings, as well as for the 2 proposed warnings that were not selected for the final rule. We note that the study was not designed, nor statistically powered, to examine effects for various groups by age (i.e., adolescent, young adult, older adults) or smoking status (i.e., nonsmokers, smokers). Results are presented for the overall sample for all 10 outcome measures:

- Whether the warning was new information to participants ("new information");
- Whether participants learned something from the warning ("self-reported learning");
- Whether the warning made participants think about the health risks of smoking ("thinking about risks");
- Whether the warning was perceived to be informative ("perceived informativeness");
- Whether the warning was perceived to be understandable ("perceived understandability");
- Whether the warning was perceived to be a fact or opinion ("perceived factualness");
- Whether participants reported beliefs linking smoking and each of the health consequences presented in the warning ("health beliefs");
- Whether the warning was perceived to help participants understand the negative health effects of smoking ("perceived helpfulness understanding health effects");

- Whether the warning grabbed their attention ("attention"); and
- Whether the warning was recalled ("recall").

Prior to conducting the study, FDA conducted a power analysis, which is a test to ensure that the overall sample size would adequately detect study effects should they exist. The power analysis allowed FDA to determine the optimal sample size and allocation of the sample across the study conditions, which informed the study sample. FDA expected it to be harder to find effects on the "health belief" outcome measure than on the other measures (including the "new information" and "self-reported learning" measures that FDA specified as predictive of improved understanding), and therefore powered the study on the estimated "health belief" effect size in order to ensure sufficient robustness to detect statistically significant differences. In particular, for the overall sample size, FDA calculated power to detect a statistically significant difference in the change in a health belief from Sessions 1 to 2 between the treatment and the control groups.

2. Use of FDA's Final Consumer Research Study Results in the Selection of Required Warnings

As discussed in section VII of the proposed rule, we identified 13 cigarette health warnings for the proposed rule. All proposed warnings were factual and accurate, advanced the Government's interest, were not unduly burdensome, and demonstrated statistically significant higher levels of providing new information and self-reported learning when compared to the control condition (i.e., the Surgeon General's warnings) (Ref. 17). We stated that we intended to finalize some or all of the 13 proposed warnings and that, in determining which proposed warnings would be required in the final rule, FDA would consider public comments submitted to this docket, full research results from our final quantitative consumer research study (including peer reviewer comments), the scientific literature, and other considerations.

Since the publication of the proposed rule, FDA has continued to review and evaluate this study's results. Those results, discussed in more detail in section VII, strongly support our determination that the final required warnings will improve understanding of the negative health consequences of smoking. All 11 of the final required warnings demonstrated statistically significant improvements over the current Surgeon General's warnings (the control condition in the study) on these 8 outcomes: new information, self-reported learning, thinking about the health risks of smoking, perceived informativeness, perceived understandability, perceived helpfulness understanding health effects, attention, and recall (see Ref. 17 for more information about the study).

As described in section V.B of the proposed rule, understanding is multifaceted and composed of multiple processes. Consumer perceptions that a warning provides new information and can contribute to self-reported learning are necessary precursors to message comprehension and learning (Refs. 61, 206, and 207). An important first step in promoting public understanding of health risks is therefore to raise public awareness of those risks, particularly if the risks are not commonly known (Refs. 209 and 210). FDA determined that, to be considered for the final rule, a tested warning would need to demonstrate statistically significantly better performance than the control (the current Surgeon General's warnings) on these two "new information" and "self-reported learning" outcome measures as predictive for promoting understanding of the risks associated with cigarette smoking.

Other outcome measures were "perceived informativeness," "perceived understandability," "perceived factualness," and "perceived helpfulness in understanding health effects." These measures capture study participants' reactions to and judgment of a message (Ref.

61). In turn, an individual's judgment of a warning is linked to increased likelihood that the warning is understood (Refs. 208 and 211).

The "health beliefs" and "thinking about risks" outcome measures capture study participants' ability to process and think about the information in a message, which subsequently leads to knowledge acquisition and learning (Ref. 206). Warnings that promote accurate health beliefs and thinking about the health risks of smoking are more likely to lead to understanding about the negative health consequences of smoking compared to warnings that fail to promote these indicators.

Two other outcome measures, "attention" and "recall," capture study participants' attention to a warning and their ability to recognize or recall the warning (Refs. 61 and 206). A warning that is noticed and attracts sufficient attention for information to be encoded and recalled increases the likelihood of understanding the warning compared to a warning that does not attract attention (Refs. 34, 207, and 208).

As noted above, all 11 final required warnings outperformed the current Surgeon General's warnings on 8 of the 10 outcome measures, including the two that FDA determined were predictive of improved understanding (i.e., "new information" and "self-reported learning"). On the "health beliefs" outcome, nearly all (9 of 11) of the final required warnings also demonstrated statistically significant improvements over the Surgeon General's warnings between Session 1 of the study and Session 2, approximately 1 to 2 days later, and many (7 of 11) of the required warnings also demonstrated statistically significant improvements over the Surgeon General's warnings on changes in health beliefs between Session 1 of the study and Session 3, approximately 17 days later. As noted in section VI.C.3 of the proposed rule, 84 FR at 42769, health beliefs may be unlikely to change with limited exposures, as was seen in FDA's

first quantitative consumer research study (see Ref. 12). In FDA's final consumer research study, which had just two brief exposures to the tested warnings over 2 days, measurable changes in health beliefs were not expected (see, e.g., Refs. 205 and 206). That FDA's final consumer research study found changes in health beliefs between Sessions 1 and 2 for 9 of the 11 final required warnings, and that those changes persisted for an additional 2 weeks for 7 of the 11 final required warnings, demonstrates that even with two brief exposures, the cigarette health warnings influenced participants' beliefs about the negative health consequences of smoking.

On one of the 10 outcomes in our final consumer research study, "perceived factualness," the cigarette health warnings did not reliably outperform the current Surgeon General's warnings. All tested warnings (both the 16 tested cigarette health warnings and the 4 current Surgeon General's warnings, which served as the control condition) were rated as factual by the vast majority of participants. Four of the final required warnings, however, were not perceived as factual to a degree that was statistically significantly more or less than the Surgeon General's warnings. The remaining required warnings were perceived as factual statistically significantly less than the Surgeon General's warnings. Such a finding is common in pre-implementation studies that test warnings about health effects for which there are low levels of consumer awareness (Refs. 4, 43, and 78). As explained in the responses to comments later in this section (see section VI.B.2), individuals presented with new information may view it with skepticism and even consider the new information less factual than information they have seen before (Refs. 70–77).

Beyond looking at statistical significance, FDA also considered the strength and consistency of the findings across all outcomes. Although we found some variation in the effect of each of the tested required warnings on some study outcomes, this is to be expected as there

was a diverse representation of health topics across the warnings. In addition, as mentioned above and in the proposed rule, differing levels of baseline knowledge among participants about the various health conditions would contribute to the variation found in the effects across the required warnings.

In any event, the consistent pattern of findings for each individual required warning *and* across all the required warnings is highly supportive. For example, we assessed participants' ability to recall the warning they had previously been exposed to in the study. Participants viewed four warnings in random order, one of which they had previously been shown; thus, participants had a one in four (25 percent) random chance of correctly guessing the warning they had previously been shown. Participants who were shown one of the 4 Surgeon General's warnings recalled which warning they were shown at levels very similar to what they would achieve through chance guessing (25.7 percent recall). By contrast, the tested cigarette health warnings were recalled substantially more, with recall ranging from 49.4 to 73.9 percent, depending on the specific required warning.

Although not conducted with a nationally representative sample, which prevents direct extrapolation of the study findings to the U.S. population, the size and consistency of the effects found in our final consumer research study demonstrate that the required warnings will promote greater public understanding of the negative health consequences of smoking.

B. Responses to Comments Regarding FDA's Approach

FDA received numerous comments in the docket related to its approach to developing and testing new cigarette health warnings depicting the negative health consequences of smoking, which we summarize and respond to in the following paragraphs.

1. Overall Iterative Research Process

(Comment 33) Several comments support FDA's science-based, iterative research process, stating that it shows that the research was strong and demonstrates that the proposed required warnings will lead to greater public understanding of the health harms of smoking and that the proposed rule is well supported and justified. Comments note the comprehensive list of scientific references used to provide robust evidence for the support of cigarette health warnings in promoting understanding as well as the set of qualitative and quantitative consumer studies that FDA conducted. However, some comments object to the research and development process, for example, stating that FDA "has not developed record evidence which supports the choice made," and that the proposed rule "constitutes regulation on the basis of speculation, conjecture, or supposition--based on either: (1) a hypothetical reduction in smoking not supported by the record; or (2) a hypothetical problem, lack of consumer awareness of the harms of smoking."

(Response 33) We disagree with the comments that suggest the rule is based on speculation, conjecture, and supposition. As described in detail in the proposed rule, and as many comments recognize, the rule is the result of a science-based, iterative research process across all phases of research and development of the required warnings that would advance the Government's substantial interest in promoting greater public understanding of the negative health consequences of smoking. In addition, contrary to the suggestion of at least one comment, the Government's interest in this rule is not to reduce smoking rates, but rather it is to promote greater public understanding of the negative health consequences of smoking. We discuss the Government's interest for the final rule in detail at section IV.C.1.

(Comment 34) One comment, from an internationally recognized expert in developing and testing cigarette health warnings who submitted on behalf of a public health group, summarizes and evaluates FDA's process for developing and testing the proposed required

warnings, the regulatory objectives of the proposed rule, and the proposed rule's potential burden on industry. The comment ultimately concludes that FDA's regulatory objectives are clearly articulated and appropriate; FDA has engaged in a comprehensive and rigorous research process to develop and test the proposed required warnings; findings from FDA's studies highlight substantial gaps in existing health knowledge among consumers; the current 1984 Surgeon General's warnings on cigarette packages and in cigarette advertisements fall well below minimum international standards; findings from FDA's studies reinforce the importance of using graphic images to communicate the health effects of smoking; the design of the proposed required warnings is consistent with the scientific literature on effective design principles; the size of the warnings is appropriate and necessary to achieve FDA's objectives; and the proposed required warnings do not "unduly" restrict manufacturers' ability to convey other information on packages or advertisements. The comment further states that the findings from FDA's consumer research studies are highly consistent with the extensive evidence from "post-implementation" studies that have assessed the impact of pictorial cigarette warnings in other countries. The comment also considers the potential limitations that FDA identified with the studies, such as the use of an online survey and the decision made about the appropriate comparison group, and concludes that these potential limitations do not prevent the findings from providing strong support for the proposed warnings.

(Response 34) FDA agrees with this supportive comment that the research and development process was rigorous and adhered to best practices for the conduct and reporting of the studies and that the potential limitations we identified do not prevent the study findings from providing strong support for the proposed required warnings. We also agree that the studies and

other scientific analysis in the proposed rule strongly support both the need for the rule as well as the ability of the rule as designed to meet the Government's objectives.

(Comment 35) At least one comment objects that FDA provided no evidence in the proposed rule to support why the Agency selected particular color graphics to illustrate the textual warning statements, including whether it considered alternative graphics to illustrate the same concepts or why it chose the selected photorealistic illustrations over others that could have depicted the same health conditions described in the textual warning statements.

(Response 35) As described in detail in section VI.D of the proposed rule, FDA undertook an iterative, research-based approach to develop color graphics depicting the negative health consequences of cigarette smoking to accompany the textual warning statements. This process required considering findings from health communication science research regarding best practices for helping the public better understand health risk information and testing potential text statements, potential images, and potential pairings of text statements with images to ensure that the final required cigarette health warnings are unambiguous, are unlikely to be misinterpreted or misunderstood by consumers, and do convey factually accurate information.

Research indicates that multiple factors influence whether a specific type of visual depiction (such as an image compared to a bar chart or graph) ultimately aids or impedes message comprehension, including the level of concordance between the text and accompanying visual depiction (e.g., using an image of an eye to depict the word "eye"); the level of cognitive effort required to understand the information (e.g., using a stacked bar chart to depict multiple data comparisons requires greater cognitive effort); and the type of communication channel used to deliver the message (e.g., information presented by a doctor as part of a conversation with a patient, versus information presented in a mass media campaign) (Refs. 79–89). For example, in

comparison to bar charts or graphs, visual depictions in the form of illustrations or photographs are more likely to aid comprehension when used for mass-communication purposes because these types of visual depictions are more easily made congruent (i.e., the type of visual is appropriate for the message) and concordant, and they require less numerical proficiency and cognitive effort to understand the information (Refs. 81, 82, 86, and 87).

Based on our review of the literature, the cigarette health warning message content, and the communication channel, FDA determined that textual warning statements paired with factually accurate, concordant photographs or photorealistic images of specific health conditions, presented in a realistic and objective format, would be most likely to advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. FDA ultimately used a photorealistic illustration format for the images because this format best allowed FDA to ensure that the final images would be fully concordant with the ultimate textual statements addressing the same health conditions. The photorealistic illustration format also facilitated providing factually accurate images that depict common presentations of the health conditions in a realistic and objective format devoid of non-essential elements.

In terms of determining what to depict in the photorealistic illustrations, FDA consulted the medical literature and internal Agency medical experts to identify common, visual presentations of each health condition described by the textual warning statements. FDA then developed a larger set of potential warning images, which were subsequently refined and reduced, including with feedback from various qualitative focus groups and interviews, to the set of 16 text-and-image pairings that were included in the second large quantitative consumer research study.

2. Quantitative Studies

(Comment 36) One comment suggests that FDA's two quantitative consumer research studies were not credible because they did not go through a peer review process.

(Response 36) We disagree with this comment. As stated in the proposed rule, we placed in the docket for public comment two study reports that described FDA's quantitative consumer research studies and presented the results of the analyses from the studies. In developing this final rule, we considered comments on those study reports. In addition, as discussed in the proposed rule, both studies were also undergoing a peer review process, which is now complete. The peer reviewers included six experts in behavioral science (psychology, public health behavior, tobacco control/tobacco regulatory science, and health communication). The peer reviewers concluded that the studies were strong and that "both studies are very well done in terms of design and data analysis" and "appropriate to address the study's purpose." Peer reviewers provided comments to improve the clarity of the study reports and provide additional details. The external peer review report is available on FDA's "Completed Peer Reviews" website at <https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews>. Following consideration of the peer review comments, FDA updated the study reports accordingly, including adding clarifying details about the studies' procedure and analysis, but none of these updates to either study report changes the results, findings, or conclusions of either study, nor do any of the updates affect FDA's decisions that relied in part on these studies. The final peer-reviewed study reports are included in the docket to this final rule (Refs. 12 and 17).

(Comment 37) One comment asserts that FDA's two quantitative consumer research studies suffered from study design flaws and are inherently biased. The comment states that both

studies compare new, more specific information in the proposed required warnings to the more general statements contained in the nine TCA statements and in the four Surgeon General's warnings. The comment argues that comparing highly detailed statements to more general statements may artificially inflate study participants' self-reported measures of learnings or new information by conflating specificity and length of the new statements with knowledge. Another comment, however, states that new knowledge among participants in the experimental conditions of FDA's studies is a logical and reasonable consequence of the potential real-world implications of displaying specific versus general health effects. Additionally, this comment states that information about specific health effects typically conveys more information and may produce more specific health knowledge, which is consistent with FDA's study findings that indicate that participants who were shown the revised textual warning statements and new cigarette health warnings reported greater scores in "new information" and "self-reported learning" when compared to the control participants.

(Response 37) FDA disagrees with the comment that the two quantitative studies suffer from design flaws and are inherently biased. Rather, as pointed out by other comments, the study design yields valid findings that exposure to the specific information contained in the required warnings promotes greater understanding of the negative consequences of smoking when compared to the broad statements contained in the warnings to which they are compared.

(Comment 38) Other comments object that FDA has not demonstrated that the required warnings will promote public understanding of the negative health consequences of smoking due to the limitations of the study measures "new information" and "self-reported learning." One comment asserts that these study measures do not reflect increased learning and understanding

and that FDA fails to demonstrate how these measures can reflect understanding via mentally processing, reflecting on, and thinking about the harms of smoking.

(Response 38) FDA disagrees with the comment that relying on the measures of "new information" and "self-reported learning" prevent scientific support for the required warnings in advancing the Government's purpose of promoting public understanding of the negative health consequences of smoking. As described in section V.B of the proposed rule, 84 FR at 42762-65, FDA undertook an in-depth review of the scientific literature to determine that cigarette health warnings that provide new information and lead to learning promote understanding about the negative health consequences of smoking. In addition, as also described in V.B of the proposed rule, 84 FR at 42762-65, understanding is multifaceted and composed of several processes such as attention, acquiring new information, learning, knowledge, thinking about the message (i.e., cognitive elaboration), and recall. FDA's final consumer research study supports the effectiveness of the required warnings in promoting understanding across these various measures, as the study's findings indicate that, overall and relative to the average of the Surgeon General's warnings (i.e., the control condition), all of the new required warnings were reported to be "new information" and resulted in greater "self-reported learning." Because the required warnings outperformed the Surgeon General's warnings on "new information" and "self-reported learning"--the two outcome measures that FDA specified as predictive of improved understanding--as well as six other measures of understanding (i.e., thinking about health risks of smoking, attention to the warnings, perceived informativeness, perceived understandability, perceived helpfulness in understanding health effects, recall), the study results demonstrate that the required warnings will promote greater public understanding of the negative health consequences of smoking.

(Comment 39) Some comments assert that FDA's "new information" and "self-reported learning" measures are susceptible to social desirability bias (i.e., that participants respond in a way they think they "should" respond rather than their actual responses). However, another comment finds the measures used in FDA's consumer research studies were "appropriate to address the research questions and have been adapted from previous research to the extent possible," were standardized across conditions and respondent subgroups, and where scales were created, there was sufficient rationale and details on the construction and analysis of the scales.

(Response 39) FDA disagrees that the "new information" and "self-reported learning" outcome measures in its consumer research studies are susceptible to social desirability bias, and we instead agree with the comment that the measures were appropriate to address the research conditions. As explained in the proposed rule and in the consumer research study final reports (Refs. 12 and 17), FDA reviewed the existing scientific literature on methods, design issues, and outcome measures used in other studies seeking to improve consumer knowledge and to correct misperceptions about the health risks of cigarette smoking. As we noted in the supporting statement for the information collection requests approved by the Office of Management and Budget (OMB), the measures used in both studies were drawn from previously used and/or validated instruments to ensure that instruments are not ambiguous, burdensome, or confusing (OMB control numbers 0910-0848 and 0910-0866). Finally, because of the experimental design of these studies and randomization of participants to conditions, any potential social desirability bias in participants' responses would be equally distributed among the conditions (including the control condition) thus minimizing any impact of any potential bias on the results.

(Comment 40) One comment states that FDA's final consumer research study failed to show that cigarette health warnings promote understanding due to health beliefs scores measured

at Sessions 2 and 3. The comment claims that five of the warnings reduced respondents' knowledge about relevant health risks, and seven of the remaining eight warnings saw sharp decreases in knowledge gains between Sessions 2 and 3. Another comment acknowledges the challenges with changing health beliefs in study interventions with limited stimuli exposure and shorter study duration.

(Response 40) We disagree with the comment that concluded that our final consumer research study fails to show that the proposed required warnings promote understanding. Overall, the failure to detect differences in some of the outcomes assessed in the final quantitative consumer research study should be interpreted within the context of its experimental design, which collected data on 10 different measures. FDA is appropriately prioritizing the outcomes that provide the best assessment of initial reactions ("new information" and "self-reported learning") over more "delayed" outcomes that are unlikely to change after only brief exposure to a warning ("health beliefs"). In any event, findings from the study indicate that the required warnings promote gains in health beliefs, as 11 of the 13 proposed required warnings (and 9 of the 11 final required warnings) showed greater gains in health beliefs between Sessions 1 and 2 than the Surgeon General's warnings, and, even though the study was not powered to detect changes between Sessions 1 and 3 on this measure, 7 of the 13 proposed required warnings (and 7 of the 11 final required warnings) did so. In general, health beliefs may be unlikely to change with limited exposures, as was seen in FDA's first quantitative consumer research study, which measured outcomes based on a single exposure. For FDA's final quantitative consumer research study, which only included two exposures, significant changes in health beliefs were not expected (see, e.g., Refs. 205 and 206). That the final study found statistically significant changes in health beliefs between Sessions 1 and 2 for nearly all of the final required warnings,

and that such changes persisted for an additional 2 weeks for 7 of them even though the study was not powered to find such changes by Session 3, demonstrates that even with limited exposure, the warnings influenced participants' beliefs about the negative health consequences of smoking.

Moreover, the conclusions made by the comment are inaccurate and misrepresent the study findings. For example, FDA is unable to find in the report or to replicate the values provided by the comment that purportedly show reductions in study participants' knowledge about health risks. FDA is similarly unable to replicate the comment's precise calculations regarding decreases in health beliefs scores between Sessions 2 and 3. In addition, as acknowledged by the other comment, there are challenges with changing health beliefs in study interventions with limited stimuli exposure and shorter study duration.

(Comment 41) A few comments state that FDA's consumer research studies fail to support the proposed required warnings, because there were instances where FDA's warnings did not improve certain outcomes measured such as "perceived believability" or "perceived factualness." Another comment, however, observes that the inverse association between the "novelty" of a health warning and its believability is a common finding in pre-implementation studies that test warnings for health effects for which consumers have low levels of awareness, citing supporting studies, and notes that the inverse association between novelty and credibility reflects the normal cognitive process that occurs when individuals integrate new information into their existing belief system. This comment notes that these findings from FDA's studies showing lower levels of perceived believability or perceived factualness should not be generalized beyond the pre-implementation settings as research shows that cigarette health warnings implemented on

packages are perceived as highly credible and that the believability of new health warnings increase over time.

(Response 41) FDA disagrees with the comments that suggest the studies fail to support the proposed required warnings because there were no effects for a small number of outcomes measured, e.g., "perceived factualness." When individuals are presented with new information, this new information may be viewed with skepticism and perceived as less factual than information that is familiar or well-known; this finding was acknowledged by the comment speaking to the inverse association between "novelty" or newness of a health warning and its believability. When presented with new information, individuals may rely on certain common mental heuristics to aid judgment and decision making, though reliance on these heuristics can sometimes lead to judgment errors or biases (Refs. 70–77). Participants in FDA's consumer research studies may have relied on these types of heuristics to make judgments about the "perceived factualness" of the warnings tested in the study based in some measure on the "novelty" or newness of the new cigarette health warnings versus the familiarity of the current 1984 Surgeon General's warnings. As discussed in section V.A of the proposed rule, the Surgeon General's warnings have been displayed on cigarette packages for more than 35 years and are part of many smokers' previously held beliefs, further supporting the need to convey new information to the public that is not known about the health consequences of smoking. It is also important to emphasize that perceived factualness as measured in FDA's final consumer research study was assessed with an item telling participants, "Next, we would like to know whether you think this warning is an opinion or a fact. Opinions are judgments or feelings that *cannot* be proven true or false. Facts are statements that *can* be proven true or false," and then asking participants, "Would you say that this warning is opinion or fact?" This outcome measure has

nothing to do with the *actual* factual accuracy of the content of cigarette health warning (see earlier in this section for more discussion on our final consumer research study; Ref. 17). FDA unequivocally found that each of the warning statements is factual and uncontroversial, based on extensive scientific evidence.

(Comment 42) One comment suggests that FDA fails to address the potential for the cigarette health warnings to "backfire" (e.g., will be avoided) and that "highly graphic" warnings may lower levels of recall compared to warnings with less graphic content.

(Response 42) FDA did not design the required warnings to evoke negative emotions. Rather, through the Agency's science-based, iterative research process, the required warnings were designed to be factually accurate, to make the textual statements and accompanying images depicting the specific health conditions concordant, and to present the information in a realistic and objective format (see section VII.B for further discussion of the required warnings). We disagree that the required warnings will lead to low levels of recall of the content in the warnings. To the contrary, findings from FDA's final consumer research study show that, relative to individuals who viewed the Surgeon General's warnings (i.e., the control condition), individuals who viewed a cigarette health warning were much more likely to accurately recall the warning they saw.

(Comment 43) Some comments question FDA's use of non-nationally representative samples in its consumer research studies, suggesting that this limits the usefulness of the studies. Another comment, however, states that "many non-probability based samples can provide a diverse, heterogeneous sample" (citing Refs. 90 and 91) and "[a]lthough participants in a commercial panel may differ from the general population, the sociodemographic profile of the FDA study sample indicates considerable diversity based on sex, education, race/ethnicity, and

income level." In addition, this comment notes that generally, non-probability samples are acceptable for randomized trials, such as the FDA experiments. This comment concludes that overall, the study sampling designs and recruitment from both studies are appropriate for the study objectives and the analysis plan.

(Response 43) We disagree with the comments that suggest that the non-nationally representative samples used in our consumer research studies limit the usefulness of the studies in demonstrating that the required warnings will promote greater public understanding of the negative health consequences of smoking. We do agree, however, with the other comment that states that an experimental design does not require a nationally representative sample to demonstrate a valid and reliable effect. FDA set specific recruitment targets for the number of study participants in each age group and tobacco-use category to be recruited into the study population to ensure that the study results would be potentially applicable to multiple age and tobacco user groups. With respect to the study samples for Studies 1 and 2, the large heterogeneous samples allowed FDA to test outcomes across a range of individuals, thus strengthening the conclusions and applicability of the study findings, and were appropriate for the objectives of FDA's consumer research. Further, the tests of the specific textual warning statements in FDA's first quantitative consumer research study and the cigarette health warnings (i.e., text plus image) in FDA's final quantitative consumer research study represent some of the largest experimental studies on cigarette warnings conducted to date.

(Comment 44) Another comment asserts that FDA's final consumer research study is flawed because FDA did not incorporate the commenter's suggestions regarding demographic and other factors in its comment submitted related to FDA's information collection request for this study. However, another comment supports FDA's study design and implementation stating

that the research undertaken by FDA to inform the selection of health warnings was "comprehensive and demonstrates a high level of scientific rigour."

(Response 44) We disagree with the comments that suggest that the final consumer research study is flawed. While FDA considered the comments received on the information collection request for the study (OMB control number 0910-0866), including those submitted by the commenter, we did not adopt those suggestions (e.g., using a nationally representative sample, changing specific study questions, changing the design to better mimic real-world conditions) as they were not necessary for the purpose of the study. FDA agrees with the comment that states that FDA's research was comprehensive and demonstrated a high level of scientific rigor due to the careful consideration of the study design, methods, selection of measures, sampling strategy, and analysis.

(Comment 45) Some comments state that the final consumer research study suffered from methodological flaws, such as a small sample size, selection bias, a lack of meaningful pretesting, and a failure to mimic real-world conditions.

(Response 45) FDA disagrees with the criticism that our final consumer research study suffered from those methodological flaws. Regarding the sample size of 9,760 participants, prior to conducting the study, FDA conducted a power analysis, which we discuss in section VI.A.1.

Regarding the potential risk for selection bias in the final consumer research study, as stated elsewhere, FDA made efforts to ensure that the demographics of participants in the study population were diverse. Participants' demographic characteristics are reported in the final study report (Ref. 17).

With regard to meaningful pretesting, the measures used in the final consumer research study are well-established and/or pulled from validated instruments for communication and

social science research focused on general health warnings or cigarette warnings, specifically. FDA reviewed studies assessing warnings for consumer products (including tobacco and cigarette health warnings), which informed the selection of the items in the proposed study.

The health belief items assess knowledge of the specific content in the warning statements. The language and wording used in these items were derived from the specific language used in the warning statements, which underwent formative, qualitative testing with adult current smokers, adolescent current smokers, and adolescents susceptible to cigarette smoking (OMB control number 0910-0674, "Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions," which assessed reactions and understanding of the draft warning statements; and OMB control number 0910-0796, "Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images," which assessed reactions and understanding of the draft warning statements that were paired with images). In addition, FDA evaluated the performance of questionnaire items and draft warning statements in its first large quantitative consumer research study (OMB control number 0910-0848). The findings from the aforementioned quantitative and qualitative studies informed the development of warning statements, revisions to those statements, the questions used to assess beliefs about the health condition included in the warnings, and the selection of measures for FDA's final consumer research study. In addition, the final consumer research study pretested the programmed questionnaire to assess potential programming issues that might have affected the quality of the data.

Finally, the final consumer research study was designed to increase the external validity of the study where possible. For example, the procedures for the study provided two exposures to the warnings (to better reflect frequent exposure in real-world conditions) and used a longer

followup time than many similar studies to assess potential longer-term and enduring influence of cigarette health warnings to better approximate conditions once the warnings are implemented. In addition, as part of the online study, participants were able to rotate a digital mockup of a cigarette package on the screen to permit viewing all sides of the cigarette package (as opposed to viewing a static image) to better approximate real-world conditions. Participants also viewed the cigarette health warning in both formats (i.e., on packages and in advertisements), which provided an appropriate presentation of the real-world display of the warnings for smokers and nonsmokers once the required warnings are implemented.

(Comment 46) One comment objects that, because FDA's final consumer research study tested the new textual warning statements and concordant photorealistic illustrations *in combination*, there is no basis to think that the "supposed improvements" are attributable in any way to the graphic components of the proposed required warnings, rather than to the new text.

(Response 46) We disagree with the comment's objection that "improvements" need to be measured separately. The purpose of the final consumer research study was to determine if new cigarette health warnings (including both text and images) would improve understanding of the negative health consequences of smoking, which the research findings do support, and is consistent with the Congress's direction that FDA issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the textual warning statements. The final consumer research study's use of the current 1984 Surgeon General's warnings as the comparison is appropriate, because it allowed for investigation of the potential effect of implementing new cigarette health warnings compared to the current state of warnings for cigarette packages and advertisements in the United States. Additionally, as noted in section V.B.1 of the proposed rule, and in other comments submitted to the docket, the scientific

evidence shows that larger cigarette health warnings containing text paired with images are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking (Refs. 4, 45–48, 54, 55, 57, 59, 61, 62, and 92-94).

(Comment 47) At least one comment states that FDA's final consumer research study fails to isolate the effect, if any, of the size and location of the warnings. The comment asserts that FDA failed to address evidence indicating that its size requirements for packaging and advertising do not advance consumer understanding. In contrast, multiple comments state that the size and location of the required warnings are appropriate and necessary to achieve FDA's objectives. These comments note that smaller, less prominent warnings on cigarette packages and in cigarette advertisements would be less effective in promoting greater public understanding of the negative health consequences of smoking. Moreover, one comment explains that "key to the effectiveness" of pictorial cigarette warnings is their size (taking up at least 50 percent or more of the cigarette package), text that clearly describes the health effects of smoking accompanied by a color graphic that demonstrates such negative health consequences, and placement on the front of cigarette packages. Another comment states that "[t]he scientific evidence conclusively shows that graphic health warnings are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking," and that "[r]esearch also shows that size plays a key role in the effectiveness of graphic warnings--larger graphic health warnings are more effective. Warnings must be large enough to be easily noticed and read, and should be as large as possible." Similarly, another comment gives evidence to support the necessity of the warnings in their required size and location, explaining that "[t]he size of a health warning has an important influence on its ability to communicate health information." This comment also explains that the size is necessary to include important

detail depicting the negative health consequences of smoking, something research on health warnings on cigarettes and other consumer products has demonstrated consumers seek, and which increases comprehension.

Additionally, another comment from a group of health psychologists tested the impact of the proposed required warnings in their proposed size and location as compared to warnings using only the proposed textual warning statements without an image. That study reported that, compared to the text-only warnings, FDA's proposed required warnings rated higher on perceived new knowledge and understandability, providing further empirical support for the size of the required warnings. In addition, a comment submitted by another group of academics described an analysis of a longitudinal cohort survey data from 13 (non-U.S.) countries to assess changes in adult smokers' knowledge of the health effects of cigarettes before and after implementation of pictorial cigarette warnings. Pictorial cigarette warning size requirements and placement on the front and back of packages varied by country. Analysis provided by the comments concluded that pictorial cigarette warnings that are large and appeared on both the front and back of cigarette packs were more effective for increasing health knowledge.

(Response 47) We agree with the comments stating that the size and location of the required warnings on cigarette packages and in cigarette advertisements are appropriate and necessary to advance the Government's interest of promoting greater public understanding of the negative health consequences of smoking, and that the communicative value of the size and location requirements also are amply supported by evidence (see previous comment response for additional references to this body of scientific literature). Moreover, as required by section 4 of the FCLAA, as amended by the Tobacco Control Act, the required warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the

front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements. As described more fully in section V.A of the proposed rule, the existing Surgeon General's warnings have been shown to go unnoticed or to fail to convey relevant information regarding the health risks of smoking, resulting in significant portions of the population that misunderstand or underestimate the health risks of smoking. The new size and location of the required warnings, as specified by statute, are needed to increase the noticeability of the required warnings in order to promote greater public understanding of the negative health consequences of smoking. The remaining 50 percent of the principal panels of product packages and the remaining 80 percent of product advertisements provide ample space for manufacturers' speech.

(Comment 48) One comment asserts that FDA failed to meaningfully address the differential effect the proposed required warnings may have on specific subpopulations. The comment states that failure to consider subgroup differences in the consumer studies can potentially impact the effectiveness of cigarette health warnings. The comment also cites research purportedly showing that cigarette health warnings lead to unintended responses among vulnerable subpopulations. Other comments, however, provide general support for the potential impact of the required warnings on socially disadvantaged groups who may possess lower knowledge of the health risks of smoking due to lower health literacy and limited access to information about the hazards of smoking. These comments state that cigarette health warnings, paired with images, depicting the harms of smoking increase the accessibility of warnings and may help to reduce disparities in health knowledge about the harms of smoking among these disadvantaged groups.

(Response 48) The purpose of FDA's two large quantitative consumer research studies was to assess whether new cigarette health warnings promote consumer understanding of the negative health consequences of smoking, not to understand the broad effects of the warnings on different populations. Although participants with various demographic and tobacco use statuses were included in the consumer research studies, the studies were not designed to examine differences in outcomes by those subgroups. The primary analyses focused on whether new cigarette health warnings increase understanding of the negative health consequences of smoking in the overall sample, and the findings support that conclusion. In exploratory subgroup analyses, findings were similar across subgroups, demonstrating the robustness of these findings.

Regarding the comment's summary of the results of scientific studies that showed a number of differential effects cigarette health warnings may have on subpopulations that vary by demographic or tobacco use statuses, none of these studies examined whether cigarette health warnings have effects on understanding of the negative health consequences of smoking. Rather, these studies examined other outcomes, including emotional reactions to the warnings, effects on intentions to quit smoking and quit attempts, and whether the warnings deter cigarette purchase, among others. Those outcomes, however, are not aligned with the Government's interest in this rule, which is to promote greater public understanding of the negative health consequences of smoking. None of the scientific studies referred to in the comment provide direct evidence suggesting that cigarette health warnings have differential effects on consumer understanding of the negative health consequences of smoking among vulnerable subpopulations. On the contrary, as described in section V.B.2.c of the proposed rule, scientific evidence suggests that pictorial cigarette warnings increase understanding of the health consequences of smoking across diverse settings and countries and are effective for diverse populations (Refs. 15, 45, 50, and 94–99),

likely reducing disparities found in consumer understanding about the harms of smoking for some populations such as those with lower health literacy. For example, a study of U.S. consumers found that pictorial cigarette warnings were considered to be more attention-grabbing and more credible compared to text-only warnings; these effects were consistently observed across all subgroups, including racial/ethnic minorities, those with lower levels of education, and those with lower SES (Ref. 100). We agree with the general comments supporting the importance of the proposed required warnings and that they may help reduce disparities in health knowledge.

(Comment 49) Some comments assert that pictorial cigarette warnings do not promote greater understanding of the negative consequences of smoking. One comment cites research studies and asserts that these studies conclude that graphic warnings do not change people's beliefs about the harms of smoking.

(Response 49) FDA disagrees that pictorial cigarette warnings do not promote greater understanding of the negative health consequences of smoking. There is a substantial body of evidence to support their effectiveness. As explained in section V.B of the proposed rule, to understand a message, individuals must first attend to the message (i.e., notice and be made aware of the message), and then they must process the information in the message (i.e., acquire knowledge of and learn that information) (Ref. 41). These processes contribute to engagement with the message and lead to understanding. The important role of attention in message storing and processing is well supported by research (see, e.g., Ref. 101). Studies demonstrate that increasing notice of and attention to the information in a cigarette health warning promotes understanding of the message. Data from the International Tobacco Control Four Country Survey showed that noticing health warnings on cigarette packages was associated with

increased knowledge about the health consequences of smoking (Ref. 4). Smokers who reported noticing the cigarette health warnings were more likely to report believing that smoking causes the specific health consequences contained in the warnings, compared to those who did not notice the warnings.

The results of FDA's final consumer research study, outlined in more detail earlier in this section, also strongly support that pictorial cigarette warnings, including the final required warnings, improve understanding of the negative health consequences of smoking. Across almost all outcomes measured in the study, the cigarette health warnings demonstrated statistically significant improvements over the Surgeon General's warnings (i.e., the control condition in this study). This was true for all required warnings across the outcomes of new information, self-reported learning, thinking about the risks, perceived informativeness, perceived understandability, perceived helpfulness in understanding health effects, attention, and recall (see Ref. 17). All but 2 of the final required warnings ("harms children" and "COPD" paired with an image of a man with an oxygen tank) also demonstrated statistically significant improvements over the Surgeon General's warnings on changes in health beliefs between Sessions 1 and 2; and 7 of the final required warnings also demonstrated statistically significant improvements over the Surgeon General's warnings on changes in health beliefs between Sessions 1 and 3, approximately 17 days later. As noted in section VI.C.3 of the proposed rule, health beliefs may be unlikely to change with limited exposures, as was seen in FDA's first quantitative consumer research study (see Ref. 12), which measured outcomes based on a single exposure. For FDA's final quantitative consumer research study, which only included two exposures, statistically significant changes in health beliefs also were not expected. That the final study found statistically significant changes in health beliefs between Sessions 1 and 2 for most

warnings tested, and that such changes persisted for an additional 2 weeks for 7 of the warnings, demonstrates that even with limited exposure, the warnings still influenced study participants' beliefs about the negative health consequences of smoking. Another comment states, "[t]he high threshold for changing health beliefs after brief exposure to a health warning makes the findings of [FDA's final quantitative consumer research study] all the more remarkable: brief exposure to a graphic warning led to greater changes in health beliefs after 1-2 days for 11 out of 16 warnings, and for 7 out of 16 warnings at two-week follow up."

Finally, the comments cite studies that they assert show that pictorial cigarette warnings do not change people's beliefs about the harms of smoking. FDA has already acknowledged some of these studies in the proposed rule (see, e.g., Refs. 47, 102, and 103), and, as previously discussed, we believe that the failure for the pictorial cigarette warnings tested in those studies to impact health beliefs is partly (but not entirely) due to the high preexisting knowledge of the particular smoking harms found in the warnings used in those studies (e.g., many people are aware that smoking causes lung cancer). In addition, one comment cites a study (Ref. 104) that compared "aversive" images of health effects of smoking to "relatively mild" images (e.g., wrinkled apple) to examine visual attention to the warnings, attitudes toward smoking, and quit intentions. That study focused on intentionally aversive images and measured attitudes and behavior, neither of which align with the design of FDA's images, the outcomes measured in FDA's consumer research study, or this rule. In part because the required warnings communicate some of the less-known and less-understood health harms of smoking, the required warnings are unlike those considered in the studies and will promote greater understanding. This view is supported by the findings of the final quantitative consumer study.

3. Qualitative Studies

(Comment 50) FDA received several comments addressing the qualitative studies.⁵ Some comments suggest that the qualitative studies "raise further questions about whether the proposed graphic health warnings will effectively improve public understanding of the health consequences of smoking." These comments also suggest that the qualitative study reports "reinforce [the] position that the proposed warnings violate the First Amendment because . . . they appeal to viewers' emotions rather than conveying factual information and restrict far more speech than necessary." The comments point, in part, to certain statements from individual participants in the qualitative studies as evidence that the proposed required warnings being considered by FDA were confusing and misleading, and further argue that, by electing not to make the changes suggested by these individual commenters, FDA improperly ignored this evidence. The comments also point to individual statements regarding the scope of the warnings and argue that FDA ignored evidence that the proposed required warnings were broader than necessary. The comments also suggest that FDA failed to consider whether the proposed required warnings would remedy a real-world harm. The comments also suggest that FDA violated the APA by not making the qualitative study reports available when the proposed rule first issued and by providing only 15 days for public comment on these materials.

Other comments state that FDA's use of qualitative studies and related data was appropriate, noting that a key principle of qualitative research is that the analysis must look for patterns across responses, rather than rely on any one statement. One comment highlights that a potential pitfall with qualitative studies is to place "too much emphasis on a single quote or comment that sparks interest," noting FDA avoided this by basing its decisions on the body of findings across the studies. Another comment notes that the qualitative studies outline the

⁵ As discussed in section IV, the Agency supplemented the docket with qualitative study information and reopened the comment period for an additional 15 days (84 FR 60966).

iterative, science-based process undertaken by FDA in which the findings from the qualitative studies were used to inform the development and refinement of the warnings tested in subsequent quantitative studies.

(Response 50) We agree that our use of qualitative studies was appropriate. As we discussed in the proposed rule and earlier in this section, FDA conducted various qualitative focus groups and interviews to test and refine the textual warning statements and images and to obtain feedback on which pairings of textual warning statements and images should be selected for further study. These qualitative studies are based on small sample sizes, are not nationally representative, and do not yield data that can be generalized. The intent behind conducting these qualitative studies was primarily to explore and inform subsequent research. We disagree that a determination to not make every change suggested by individual qualitative study participants--which, in some cases, may have rendered the required warnings factually inaccurate--concedes that FDA "ignored evidence that the proposed warnings were confusing and misleading." FDA did not originally include the qualitative study reports in the docket as the rulemaking itself did not directly rely on these studies. However, because the qualitative studies were used to inform further research and development, namely, the quantitative consumer research studies, FDA has made these additional materials available as well. We addressed the APA concern earlier in this document (see section IV.D.4). And, as we discuss in detail in sections IV and VII, we disagree that the required warnings violate the First Amendment.

VII. FDA's Selection of Cigarette Health Warnings

This section discusses the 11 required warnings and the factors that influenced each selection decision, including the results from FDA's final quantitative consumer research study, the substantive comments submitted to the docket, the relevant scientific literature, and other

legal and policy considerations weighed, such as how well the warnings depict the negative health consequences of smoking.

When we issued the proposed rule, we proposed 13 cigarette health warnings, each comprising a textual warning statement paired with a concordant photorealistic image depicting the negative health consequences of smoking. The 13 proposed required warnings were made available as electronic files in PDF format and displayed in the document entitled "Proposed Required Cigarette Health Warnings--PDF Files, August 2019," which was included in the docket for the proposed rule. Consistent with section 4 of the FCLAA, two versions of each of the 13 proposed required warnings were developed--one displaying the textual warning statement in black font on a white background, and one displaying the textual warning statement in white font on a black background.

In order to determine which of the proposed cigarette health warnings to require in the final rule, we considered a number of factors, including the results from our final consumer research study (Ref. 17; see section VI.A for a general description of the study results). We carefully examined the research results for the 13 proposed required warnings on all the different study outcomes, and we provide a discussion of those outcomes for each of the required warnings later in this section. As discussed elsewhere in this preamble, based on the results of our consumer research studies, and the existing scientific literature on cigarette health warnings, we conclude that the 11 final required warnings will advance the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

We also considered the substantive public comments received in the docket related to FDA's approach to developing and testing new cigarette health warnings, including the results of our consumer research studies. We considered comments received in the docket that suggested

that we use other text or images in the required warnings; however, as discussed in more detail in the comment summaries below and in section VIII, we selected the required warnings from the set of cigarette health warnings we developed, tested, and proposed. Our consumer research studies, among other information, indicate that these required warnings will promote greater public understanding of the negative health consequences of smoking. As explained in the comment responses throughout this section, the comments submitted to the docket did not persuade us that other textual warning statements or images had sufficient support to demonstrate they would advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking.

A. General Comments on the Proposed Cigarette Health Warnings

FDA received several comments on the 13 proposed required warnings. Some comments discuss the 13 proposed required warnings generally, and we have summarized and responded to these comments in this section. The comments relating to each individual proposed required warning are discussed in sections VII.B and VII.C.

We considered the comments submitted to the docket as we determined which cigarette health warnings to require in the final rule. We evaluated the substantive input contained in the comments to help inform our decisions in selecting or not selecting a proposed cigarette health warning. Many of the comments contain information about the submitter's personal opinions related to various proposed warnings. While this information is helpful in understanding how some individuals might interpret various warnings and in raising issues for further exploration, this type of qualitative information is not as useful as quantitative assessments of the outcome measures related to increasing understanding, such as the evaluation provided in FDA's final consumer research study (Ref. 17).

In addition, we received a number of comments regarding our consumer research studies; these comments are summarized in section VI.

1. Comments Submitting Research on FDA's Proposed Required Warnings

We received some comments that described the results of scientific investigations that the submitters had conducted to evaluate the 13 proposed required warnings on various outcomes. We address that research and our responses to these comments in the comment summaries and responses below.

(Comment 51) One comment, representing a group of academic researchers, provides information on an experimental study conducted to evaluate responses to the 13 proposed required warnings in comparison to text-only equivalents among a convenience sample of 412 U.S. adult cigarette smokers, dual e-cigarette users and smokers, and nonusers of e-cigarettes and cigarettes. The reported findings include that: (1) most of the proposed cigarette health warnings enhanced understandability, perceived new knowledge, worry, and discouragement to smoke relative to text-only warnings; (2) the proposed cigarette health warnings varied in their relative impact in eliciting perceived new knowledge, worry, and discouragement to smoke compared to text-only versions; and (3) effects of the proposed cigarette health warnings were generally stronger for nonusers and dual users (i.e., those who both smoke cigarettes and use e-cigarettes) than for smokers, which the comments state were generally consistent with their previous work with young adults (Ref. 105). The comments conclude that these results are consistent with prior work on cigarette health warnings suggesting that such warnings enhance knowledge about the harms of smoking and evoke reactions that are associated with quitting smoking.

(Response 51) FDA appreciates the submission of this study using FDA's proposed required health warnings that demonstrates additional support for the ability of the proposed

required warnings to enhance public understanding of the negative health consequences of smoking as compared to text-only versions of the warnings. We note that one outcome included in the study referred to as "perceived new knowledge" is very similar to the outcome used in FDA's consumer research study referred to as "self-reported learning" and shows similarly strong effects on that outcome as in FDA's study. In addition, perceived new knowledge was the strongest effect of all the outcomes in the study, including worry and discouragement to use cigarettes. Overall, the study's conclusions are supported by the data presented, but there are some minor limitations in the design and measures that may limit generalizability to prior work and the general U.S. population. In addition, FDA notes that an assessment of emotional responses or behavioral study outcomes is not aligned with the final rule, whose purpose is to promote greater public understanding of the negative health consequences of smoking.

(Comment 52) Another comment from a cigarette manufacturer includes the findings of a web-based panel, created using a convenience sample, stating that the study serves as evidence that the required warnings were designed to evoke emotional negative reactions; were meant to convey an ideological anti-smoking message; and were not the less-restrictive alternative, as the study's findings purportedly show that textual warnings would be at least as effective as pictorial cigarette warnings. In the study, adult participants were randomly assigned into one of six conditions that varied in format, size, and location (e.g., a text-plus-image warning on the top 50 percent of the package, a text-only warning on the top 20 percent of the package, a text-plus-image warning on the side of the package). Participants were shown a random selection of 5 of FDA's 13 proposed required warnings. Afterward, participants completed measures assessing agreement with the warning, if they had previously heard about the health effects described in the warning, if they thought the warnings were communicating that they should or should not use

or purchase the product, and what message the warnings communicated. The comment's study found that, for warnings in the proposed size and location (top 50 percent of the front and rear panels of the package), between 18.9 and 65.1 percent of participants had not previously heard about the health condition in the warnings; the vast majority of participants (greater than 76.0 percent) agreed with the warning statements; and that many of the results were not different depending on the size and placement of the warnings on packages. The comment notes that the data show that many smokers in this study indicated that the warnings convey a message that they should not smoke (74 percent) or purchase the product (71 percent). The comment also reports that many smokers in this study believed the warnings are trying to make people feel disgusted (68 percent), shock people (85 percent), and make people feel distress (70 percent).

(Response 52) We appreciate the value of additional research on the potential impact of FDA's proposed required warnings, but we note that many of the outcomes assessed in this study relate to behavior and are not aligned with the final rule, whose purpose is to promote greater public understanding of the negative health consequences of smoking. The study also suffers from numerous limitations on the conclusions that can be drawn about the ability of the required warnings to promote public understanding of the negative health consequences of cigarette smoking. The limitations include that it is unclear whether each set of five warnings viewed by each participant was displayed in the same format size and location, which prevents us from drawing conclusions about the impact of size, location, and specific required cigarette warnings on outcomes relevant to understanding. Other limitations include a lack of information provided regarding sample recruitment; total sample size; study drop-out and attrition; and limited information about the sample characteristics beyond age and current smoking status. Although the comment states that the demographics of the sample were drawn to reflect the U.S.

population, there is no discussion of whether the data were weighted to the U.S. population or whether the attempt to match the U.S. population was successful. While the comment includes a description of the study with some descriptive measures (e.g., an appendix to the study includes the proportions), there is no information provided regarding confidence intervals or standard error; therefore, we are unable to determine the accuracy of the study's results (Refs. 106 and 107). Further, no information was provided as to whether there was adequate power to detect statistically significant differences between groups. It is unclear whether the null findings found for the effect of warnings compared to warnings with different formats is attributed to an actual lack of an effect of the cigarette health warnings or a lack of sufficient power to detect such effects (Refs. 108–110). Responses to one question only present results for 384 of the unknown total number of participants without providing information on participants who did not have an opinion on the question. The comment also did not provide information about the tobacco use status (e.g., never user, former user) of half of the sample, which limits the applicability of any findings. Details were not provided about the control condition, there was no image provided of the stimuli used in that condition, and no data were provided comparing the control condition to experimental conditions. Of particular concern, it is not clear if survey items were drawn from previously validated or previously used surveys, which would lend credibility to the items used and reduce the potential for measurement error.

2. Other Comments

FDA received a number of other comments that discuss the proposed required warnings generally or highlighted issues that applied to some or all of the proposed required warnings. These comments are summarized and responded to below.

(Comment 53) Numerous comments express strong support for the proposed required warnings stating, in part, that each of the required warnings convey factual information. Comments support the 13 proposed warnings, stating that the proposed warnings cover a wide range of highly prevalent health conditions and that the health conditions are supported by a broad consensus of scientific research and Surgeon General's Reports. Other comments state that the images effectively capture attention without provoking an emotional response and the textual warning messages are brief, accurate, and clearly link to the visual image.

Some comments express support for the use of strong causal language such as "causes," providing supporting scientific evidence in the required warnings, with one comment submitting a published scientific study of 1,413 adults in the United States (Ref. 111). One of these comments, which was submitted by a group of research scientists, confirms that the characteristics of FDA's proposed warnings suggest they will be effective. This comment states that FDA's proposed required warnings followed design principles and best practices in warning development that enhance their effectiveness, as follows: the warnings include human faces or diseased body parts (which, the comment notes, studies show are more effective than other types of images); the warnings have a high degree of congruency (which, the comment notes, studies show increase recall and attention); the warnings use strong causal language; and that the warnings are concise, making the warning text easier to read and understand. Another comment from a group of scientific researchers emphasizes that the proposed warnings generally appear to contain congruent image and textual components (i.e., both the image and the textual warning statement convey the same message), noting this format (congruent warning labels) is likely to be an effective means for increasing knowledge of the risks conveyed by the warnings.

(Response 53) We agree with these comments. As we describe in sections VI and VII of the proposed rule and in this section, these cigarette health warnings, as shown through robust scientific evidence, are factual and accurate and advance the substantial Government interest in promoting greater public understanding of the negative health consequences of smoking. FDA agrees that simple phrasing and the use of strong causal language in the textual warning statements is justified both by the strength of the epidemiological evidence and communication best practices.

(Comment 54) Two comments criticize nearly all the proposed required warnings for not identifying, conveying, or measuring perceptions of the baseline risk for the health conditions in the proposed required warnings. They also suggest that the absolute risk of these conditions for smokers is small and that the warnings do not convey the marginal or dose-response risk of these conditions caused by smoking, but instead misleadingly imply that the health outcomes are solely caused by smoking. The comments also state that certain warnings are misleading because they emphasize one negative health consequence rather than others with worse survival rates.

(Response 54) As described in section VII of the proposed rule, the burden of the health conditions focused on in the required warnings is substantial, and all of these health conditions are causally linked to smoking through substantial scientific evidence as summarized in various reports of the Surgeon General. Contrary to the comments' assertion, nothing in the warning text or image conveys that smoking is the only causal factor (i.e., a necessary condition), nor have the comments provided any evidence to support that point. However, for many of the required warnings, smoking is one of the strongest, if not the strongest, causal factors. For example, cigarette smoking has repeatedly been identified as the most important risk factor for bladder cancer (Refs. 112–114). The National Heart, Lung, and Blood Institute of the National Institutes

of Health states that smoking is a major risk factor for heart disease (Ref. 115), and the Centers for Disease Control and Prevention (CDC) states that smoking is one of the three key risk factors for heart disease (Ref. 116). FDA strongly disagrees that lack of communication about multifactorial causes of a disease in any way means that warnings that accurately state that smoking causes a negative health consequence are misleading.

The comment is correct that the marginal risk of disease attributable to smoking is not communicated as part of the warnings and thus that information is not assessed in FDA's consumer research studies. As stated in the documents related to collecting the quantitative information in FDA's consumer research studies (OMB control numbers 0910-0848 and 0910-0866) and section VI of the proposed rule, FDA's goal in the consumer research studies was to assess knowledge and understanding of a negative health outcome caused by cigarette smoking, not to educate the public about the absolute, relative, or dose-response risk conveyed by smoking. Thus, the outcomes included in FDA's consumer research studies were not intended to assess the absolute or relative level of perception of such risks, but rather investigated the effect that viewing the textual warning statements or proposed required warnings had on increasing understanding of the negative health consequences of cigarette smoking.

(Comment 55) One comment states that some of the proposed required warnings do not convey any relevant information beyond the content found in the TCA statements. In one example highlighted, the comment states that the required warning "WARNING: Smoking can cause heart disease and strokes by clogging arteries" conveys the exact same information as the TCA statement "WARNING: Cigarettes cause strokes and heart disease," asserting that granular information about disease mechanism does not promote understanding about the health risks of smoking. In another example, the comment argues that the required warning "WARNING:

Smoking causes head and neck cancer" conveys the same information as the TCA statement "WARNING: Cigarettes cause cancer."

(Response 55) FDA disagrees with both comments that some of the required warnings do not convey any relevant information beyond the content found in the TCA statements and with the conclusion that information about disease mechanism does not affect the public's understanding of the risks of smoking. For example, the required warning "WARNING: Smoking can cause heart disease and strokes by clogging arteries" conveys important information relevant to numerous smoking health harms: smoking causes heart disease; smoking causes strokes; smoking causes clogged arteries; and smoking causes heart disease and strokes by clogging arteries. Accordingly, all components of the required warnings, including the information related to the disease mechanism, increases public understanding of the negative consequences of smoking.

FDA also disagrees with the conclusion that providing additional information relevant to the disease (e.g., "WARNING: Smoking causes head and neck cancer") does not improve consumer understanding above related TCA statements (e.g., "WARNING: Smoking causes cancer"). The heterogenous term "cancer" refers to a collection of related yet unique diseases. In this example, the required warning would promote understanding of the causal link between smoking and two different and specific cancers: head and neck. As discussed in section V.A.3 of the proposed rule, the U.S. public is generally aware of the effects of smoking on lung cancer in smokers, while research demonstrates that the public has limited understanding of the effect of smoking on cancers outside of lung cancer. Finally, results of FDA's consumer research studies support that consumers both understand the required warnings and learn new information from them *specifically* because of the specificity of the warning used.

(Comment 56) Some comments suggest that FDA strengthen the images by making them "less glamorous," more "gross," or more "shocking" to be more in line with pictorial cigarette warnings used in other countries. One comment highlights existing research demonstrating that pictorial cigarette warnings that include "graphic, fear-arousing depictions of the impact of smoking on the body or those that use testimonial are associated with increases in motivation to quit smoking, thinking about health risks, and engaging in cessation behavior" (Ref. 117). Another comment suggested that use of a testimonial or image similar to "Christine" from CDC's "Tips from Former Smokers" campaign would likely evoke a much stronger emotional response. Other comments address levels of arousal, with one comment recommending FDA drop warnings containing images with "less arousing images [as they] will not support lasting knowledge of the associated health effects." One comment states that the images in the proposed required warnings are "adequately arousing," citing research that shows that arousal in cigarette health warnings "acts as information itself, a motivator, and an enhancer of information" (Ref. 118) and that "arousal is important for the long-term memory of the information the FDA wishes to convey" (Ref. 119). Some comments, however, object that FDA designed the new cigarette health warnings to evoke a negative emotional response and that "forcing" consumers to look at the proposed required warnings "evokes feelings of fear, shame, and disgust, and conveys the ideological message that people should not smoke." These comments also object that the proposed required warnings are not purely factual.

(Response 56) FDA disagrees that the images should be made more "gross" or "shocking," and we also disagree that FDA designed the required warnings to evoke an emotional response. The images were not designed to evoke negative emotions such as fear, shame, and disgust, but rather to promote greater public understanding of the negative health

consequences of cigarette smoking. As detailed in section VI.D of the proposed rule, FDA undertook a rigorous multistep process to develop, test, and refine images that: (1) are factually accurate; (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced; (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and (4) are concordant with the accompanying text statements on the same health conditions. The images are not intended to evoke negative emotions such as fear, shame, and disgust, but rather to promote greater public understanding of the negative health consequences of cigarette smoking. Each of the 11 required warnings in the final rule depicts a negative health consequence of smoking that is well documented in the scientific literature. To be sure, some viewers may experience the information contained in the images--which appropriately convey the serious health consequences in a factually accurate, realistic manner--as concerning; but to the extent this occurs, it will be because the severe, life-threatening and sometimes disfiguring health effects of smoking are indeed concerning.

B. Selected Cigarette Health Warnings

This section discusses the 11 required warnings and the factors that influenced each selection decision, including the results from FDA's consumer research studies, relevant scientific literature, the substantive comments received to the docket, and other legal and policy considerations weighed. Based on these considerations, FDA has determined that the 11 required warnings included in the final rule will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. As discussed in section VI.A of the proposed rule, the causal link between cigarette smoking and the negative

health consequences depicted in each required warning is rated at the highest level of the four-level classification provided in the Surgeon General's Reports.

As described in section VI of the proposed rule, FDA undertook a science-based, iterative research and development process to develop, test, and refine new cigarette health warnings that will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. This careful, science-based process resulted in the 11 required warnings that are the subject of the final rule. First, FDA undertook research to consider whether revisions to the textual warning statements specified in section 4(a)(1) of the FCLAA would promote greater public understanding of the risks associated with cigarette smoking. The empirical results demonstrate sufficient scientific support to adjust the textual warning statements (Ref. 12). Second, FDA carefully developed and tested concordant color graphics, in the form of photorealistic images, depicting the negative health consequences of smoking to accompany each of the textual warning statements. In FDA's final consumer research study, full cigarette health warnings--consisting of a textual warning statement paired with a concordant photorealistic image depicting the negative health consequence in the statement--were evaluated to assess the extent to which any of the warnings increase understanding of the negative health consequences of cigarette smoking. For warnings to be considered for the proposed rule, FDA decided that a warning tested in the final consumer research study must demonstrate statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings), on both the two outcomes of "new information" and "self-reported learning."

In the proposed rule, we stated that, after considering the full results of FDA's research, the relevant scientific literature, public comments submitted to the docket, and other legal and policy considerations, FDA intended to finalize some or all of the 13 proposed cigarette health

warnings. Based on the empirical results of FDA's research program, as well as our consideration of each of the factors discussed in this section, FDA is including the following 11 required warnings in the final rule. Because these required warnings, as shown through the robust scientific evidence described in detail in sections VI and VII of the proposed rule, are factual and accurate, advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking, and are not unduly burdensome (see section IV.B for a more detailed discussion), FDA believes the required warnings are consistent with the First Amendment, regardless of the standard of scrutiny (e.g., *Zauderer* or *Central Hudson*) under which they are reviewed.

The required warnings, each of which consists of a textual warning statement paired with a concordant photorealistic image depicting the negative health consequences of smoking, are contained in a document entitled "Required Cigarette Health Warnings, 2020" (Ref. 11), as is further discussed in section III.B.

With regard to the photorealistic images contained in the required warnings, and as described in section VI.D of the proposed rule, FDA undertook a rigorous multistep process to develop, test, and refine images that: (1) are factually accurate; (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced; (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and (4) are concordant with the accompanying text statements on the same health conditions.

FDA considered many different factors when developing the warning images, including current public understanding and gaps in knowledge of the negative health consequences of

cigarette smoking; the varied levels of health literacy and numeracy among the U.S. population; findings from communication science research regarding the types of visual depictions that are most appropriate for communicating health risk information to lay audiences; general best practices for developing mass communication efforts; the Agency's statutory requirements for cigarette health warnings under section 4 of the FCLAA (as amended by sections 201 and 202 of the Tobacco Control Act); and the practical implications of visually depicting the negative health consequences of cigarette smoking in the form of warnings on cigarette packages and in advertisements.

As a form of mass communication, cigarette health warnings must feature messages that are appropriate for the target audience, communication channel, and public health goals. In section VI of the proposed rule, we described the process for developing and testing the required cigarette warnings in detail, outlining the health communication science research findings we considered when determining how best to help promote greater public understanding of the negative health consequences of cigarette smoking. For example, the American public is a diverse population comprising individuals with many varied backgrounds, knowledge, beliefs, and abilities to read and understand health information. In fact, national surveys indicate that only about 12 percent of U.S. adults have proficient health literacy (i.e., the ability to access, understand, and use health information and services) and fewer than 10 percent have proficient numeracy levels (i.e., the ability to understand and use numbers, including the ability to read and interpret data presented in tables, graphs, and bar charts (Refs. 120–123)). Considering these differences in health literacy and numeracy levels, as well as additional factors such as the limited amount of space for additional explanatory text and graphics and the constraints of a one-way communication channel, attempting to convey complex information such as quantitative risk

measures would be incongruent with the Government's interest of increasing public understanding of the negative health consequences of cigarette smoking. Instead, best practices for health risk communication state that simple, clear, and direct messages are best understood, especially for those with low health literacy and numeracy.

Further, given the need to visually depict the content of the required warning's textual warning statements with concordant, factually accurate color graphics that promote greater understanding of the health consequences as described by the text, the majority of images appropriately depict external symptoms and disease states. FDA hired a certified medical illustrator to develop--in close collaboration with FDA staff--the high-quality, factual, medically accurate, photorealistic images. As explained in section VI.D of the proposed rule, FDA determined that photorealistic illustrations would be the most appropriate visual depiction format because this format best allowed depicting specific features of the health conditions as described by the textual warning statements. The photorealistic illustration format also facilitated providing factually accurate images that depict common presentations of the health conditions in a realistic and objective format devoid of non-essential elements. Using photorealistic images also allowed further editing and refinements for clarity and ease of understanding throughout the science-based, iterative research and development process for new cigarette health warnings.

The photorealistic images in these required warnings present the health conditions in a realistic and objective format, do not contain additional unnecessary details, and do not contain any elements intended to evoke a negative emotional response. Because these warnings are designed to educate the public about the very real, serious, and sometimes deadly outcomes of cigarette smoking, the factually accurate content may evoke subjective, emotional responses

among some consumers based on their personal history and personality characteristics. See section IV.C.2.b for a discussion of comments on this topic.

In this section's discussion of the results from our final consumer research study for each required warning, a study effect with an associated p-value below 0.05 (or $p < 0.05$) is considered to be a "statistically significant" effect. A p-value is reflective of the probability that a study finding could have happened by chance. For example, a p-value of 0.04 means that if there was no true study effect, the observed finding would still be obtained in 4 percent of studies due to chance. Having a predetermined cut off at $p < 0.05$ is a commonly used level to conclude the effect has a very low likelihood of being due to chance. In our analyses, we also use additional statistical controls (Refs. 124 and 125) to account for the number of different statistical tests computed across all warnings for all outcomes. With an increased number of statistical tests performed, more findings could happen by chance alone. Controlling for this helps to produce estimates of statistical significance that are more conservative and produce higher confidence in the results. The full description of our final consumer research study and the analyses are contained in the final, peer-reviewed study report (Ref. 17).

We describe each of the required warnings next, along with a summary of comments received and FDA's responses.

1. "WARNING: Tobacco smoke can harm your children."

This required warning consists of the TCA statement "WARNING: Tobacco smoke can harm your children" paired with a concordant, factually accurate, photorealistic image depicting a negative health consequence of secondhand smoke exposure in children. The image shows the head and shoulders of a young boy (aged 8-10 years) wearing a hospital gown and receiving a nebulizer treatment for chronic asthma resulting from secondhand smoke exposure.

In FDA's final consumer research study, this warning was reported to be new information by 40.7 percent of participants who viewed it. In section VI of the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 61.6 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (83.1 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Despite the strong results on nearly all other measures included in the study, this warning did not show statistically significant improvements in health beliefs either between Sessions 1 and 2 or between Sessions 1 and 3 over the changes in participants who viewed the Surgeon General's warnings, which is not surprising given the relatively brief exposure to the warning. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 57) Multiple comments support the inclusion of this warning in the final rule, with one comment emphasizing the importance of messages that reinforce the causal link between secondhand smoke exposure and negative health outcomes in children (e.g., impaired lung function, asthma and respiratory illnesses, sudden infant death syndrome, other preventable childhood illnesses).

(Response 57) We agree that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 58) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment questions the epidemiological evidence used to support this warning, stating that the evidence does not support the causal relationship between parental secondhand smoke and either "chronic asthma" or asthma attacks in children "requiring nebulizer treatment." Another comment states that the image does not convey purely factual information because "[n]o reasonable consumer would be able to determine from the image" that the child depicted has chronic asthma from secondhand smoke exposure or is receiving a nebulizer treatment. Rather, the comment states that the child's appearance and the mask over the child's face "suggest only that the child is experiencing a medical emergency that requires receipt of oxygen." Some comments assert that the proposed warning is "ambiguous," because it appears to depict the administration of oxygen following an asthma attack, and is an "exaggerated" or "worst case scenario" treatment for an asthma attack, because it is uncommon for a child with an asthma attack to require oxygen or to be hospitalized. One comment states that the text and image are not concordant, because the general description of a child suffering harm is not clarified by the picture, and the "ambiguity regarding the harm at issue adds to the

fear and confusion a consumer would experience when viewing the warnings." Finally, one comment states that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers, because adults viewing the image would be "horrified at the thought of inflicting such harm on their children."

(Response 58) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in section VI of the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Tobacco smoke can harm your children" is factually accurate. Tobacco smoke exposure in children is causally linked to numerous negative health consequences, including several respiratory illnesses (Refs. 3 and 126). As stated in section VII.A.1 of the proposed rule, the 2006 Surgeon General's Report on the health effects of involuntary exposure to tobacco smoke concludes that "the evidence is sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and lower respiratory illnesses in infants and children"; "the evidence is sufficient to infer a causal relationship between parental smoking and cough, phlegm, wheeze, and breathlessness among children of school age"; "the evidence is sufficient to infer a causal relationship between parental smoking and ever having asthma among children of school age"; and "the evidence is sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and the onset of wheeze illnesses in early childhood" (Ref. 126). The report also concludes that "the evidence is sufficient to infer a causal relationship between maternal smoking during pregnancy and persistent adverse effects on lung function across childhood" and "the evidence is sufficient to infer a causal relationship between exposure to secondhand smoke after birth and a lower level

of lung function during childhood." As noted in the proposed rule, more recent studies also support these same conclusions (see, e.g., Ref. 127).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The child has features consistent with chronic asthma (e.g., "allergic shiners" under the eyes), is wearing a hospital gown, and is holding a nebulizer mask. Tobacco smoke exposure can cause children who already have asthma to experience more frequent and severe asthma attacks (Ref. 126). A retrospective review of hospital-based data examining secondhand smoke exposure and asthma severity among children with asthma presenting to the pediatric emergency department (PED) showed more severe presentation and greater resource utilization in the PED for secondhand smoke-exposed children (Ref. 128). Additionally, a systematic review found that children with asthma and secondhand smoke exposure are nearly twice as likely to be hospitalized with asthma exacerbations compared to children with asthma but without secondhand smoke exposure (Ref. 129). Further, acute asthma exacerbations can be severe and may necessitate treatment, including nebulizer treatment, in an emergency department or an inpatient setting. Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that tobacco smoke can harm children. The accompanying concordant and factually accurate image depicts a child who has been harmed by tobacco smoke exposure. As stated in the preceding paragraph, it is not rare or atypical for children with chronic asthma resulting from secondhand smoke exposure to receive nebulizer treatments in either an emergency department or inpatient setting. Because the required warning

contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (e.g., hospital room setting, other medical equipment), and does not contain any elements intended to evoke a negative emotional response.

2. "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers."

This required warning consists of the TCA statement "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" paired with a concordant, factually accurate, photorealistic image depicting fatal lung disease. The image shows gloved hands holding a pair of diseased lungs containing cancerous lesions from chronic secondhand smoke exposure.

In FDA's final consumer research study, this warning was reported to be new information by 41.9 percent of participants who viewed it. In section VI of the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in

understanding the health effects of smoking. The warning was correctly recalled by 66.7 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (77.5 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition. Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 59) Some comments object to this warning because they assert it is inaccurate and misleading. For example, one comment states the image does not convey purely factual information because it does not clarify the types of lung disease nonsmokers may experience, and it is not clear that a layperson would understand that the lungs are diseased and contain cancerous lesions.

Some comments also state that the illustration does not accurately depict the lungs of "the rare never smoker who suffers from fatal lung disease due to secondhand smoke" and that the lungs "do not look like a non-smoker's lungs" due to the amount of pigmentation and the appearance of the lesions on the lungs (i.e., because such lesions would not appear on the surface of the lung and it would be unusual to have three separate lesions of the size depicted). The comments also suggest that FDA acknowledges in the proposed rule that the lung depicted is similar to the lungs of a smoker with COPD.

Another comment suggests that the warning is misleading because it emphasizes a condition that is less prevalent than other smoking-attributable health conditions. This comment also suggests that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers because the image of "blood-covered hands holding bloody diseased lungs from a deceased individual is intended to shock and disturb viewers with its goriness or to generate fear about the prospect of death and having one's lungs removed postmortem."

(Response 59) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" is factually accurate. As stated in the proposed rule, the 1986 and subsequent Surgeon General's Reports have confirmed the causal link between secondhand smoke exposure and lung cancer, a fatal lung disease, among nonsmokers (Refs. 126 and 130). The conclusion in the 2006 Surgeon General's Report extends this conclusion to all secondhand smoke exposure, regardless of location of exposure (e.g., at home, at work, in other settings); the combined evidence from multiple studies indicates a 20 to 30 percent increase in the risk of lung cancer from secondhand smoke exposure associated with living with a smoker (Ref. 126). For example, a meta-analysis of 43 studies, including studies conducted both in the United States and outside of the United States, found that the relative risk of lung cancer among nonsmoking women who live with partners who smoke (i.e., the risk of the lung cancer among nonsmokers living with smokers compared to nonsmokers not living with smokers) was 1.29 (Ref. 131). This means that

nonsmoking women who live with partners who smoke have 1.29 times higher risk of lung cancer compared to nonsmoking women who live with partners who do not smoke. Recent studies support and extend these conclusions (Refs. 132–135).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The lungs are clearly postmortem, as they have been removed from the patient's body, and the cancerous lesions and discoloration caused by vascular congestion (i.e., blood in the lower lungs causing a darker coloration) are consistent with the appearance of postmortem lungs in a nonsmoking patient with fatal lung disease.

Tobacco smoke is carcinogenic. Unlike lung cancer in smokers, lung cancer in nonsmokers targets the distal airways (Ref. 136) and is more likely to appear as depicted in the warning (i.e., discolored or darkened in the lower lungs). In comparison, postmortem lungs of a smoker would typically have a darker, almost black, coloration in the medial lungs (i.e., middle of the lungs, facing the chest) as well as other visible features that are not depicted in this image of a nonsmoker's diseased lungs. Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that tobacco smoke can cause fatal lung disease in nonsmokers. The accompanying concordant and factually accurate image appropriately depicts the postmortem lungs of a nonsmoker with fatal lung disease. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (e.g., surgical tools used to remove the lungs, background setting), and does not contain any elements intended to evoke a negative emotional response.

3. "WARNING: Smoking causes head and neck cancer."

This required warning consists of the textual warning statement "WARNING: Smoking causes head and neck cancer" paired with a concordant, factually accurate, photorealistic image depicting neck cancer. The image shows the head and neck of a woman (aged 50-60 years) who has neck cancer caused by cigarette smoking. The woman has a visible tumor protruding from the right side of her neck just below her jawline.

In FDA's final consumer research study, this warning was reported to be new information by 80.9 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 58.1 percent of participants, which

was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (71.6 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the "perceived factualness" outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 60) Some comments object to this proposed warning because they assert it is inaccurate and misleading in a number of respects. For example, one comment asserts that the image depicts an "exceedingly rare" outcome in terms of tumor size and quotes another comment that states the image implies that "a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point." Another comment states that on its own, the image does not convey purely factual information, because it is not obvious whether the growth is a tumor or something else. One comment states the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers because "the image of a woman with a large tumor protruding from her neck is disturbing and unsightly and is clearly designed to provoke disgust or discomfort at the sight of the image, fear at the prospect of experiencing the same uncomfortable medical condition, or both."

Many other comments support the inclusion of this warning in the final rule. One comment supporting the inclusion of the warning states that an estimated 53,000 new cases of cancers of the oral cavity and pharynx, which are types of head and neck cancer, will be diagnosed in 2019 and over 10,000 people will die from those cancers this year and that tobacco use is a major risk factor for these cancers (Ref. 137). Another comment provided a summary of the 1964 through 2010 Surgeon General's Reports as demonstrating strong evidence for the association between smoking and head and neck cancer.

(Response 60) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking causes head and neck cancer" is factually accurate. As many comments note, there is strong scientific support for the causal link between smoking and head and neck cancer. For example, and as described in the proposed rule (see section VII.A.3 of the proposed rule), the 2004 Surgeon General's Report stated that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and cancers of the oral cavity, pharynx, and larynx (Ref. 138), building on the strong conclusions of causality from previous reports. A more recent study (Ref. 139), submitted in a comment, that pooled data from 23 studies, found that those who smoked >0 to 3 cigarettes per day had 52 percent increased odds of head and neck cancer compared to never smokers. Those who smoked >3 to 5 cigarettes per day had 2.01 to 2.74 times the odds of head and neck cancer as compared to never smokers.

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The location (i.e., on the neck, under the jawline) and appearance of the tumor in a woman of the age pictured (50-60 years) is suggestive of a cervical lymph node metastasis (i.e., cancer in a lymph node) (Refs. 140 and 141). Cancers of the head and neck commonly metastasize to the cervical lymph nodes; therefore, the image is entirely consistent with a diagnosis of head and neck cancer (Ref. 142). Moreover, the image is very similar to other images easily found depicting the same health condition (Ref. 140 at Figure 3 and Ref. 143 at Figure 1a). Although some comments assert this image is misleading because "there would be other signs of the cancer before the patient would develop a metastasis of the size and presentation in the proposed graphic," this assertion is not accurate as not all patients with cervical lymph node metastases have other symptoms. It is not unusual for cervical lymph node metastasis to be the first symptom of head and neck carcinoma that causes the patient to seek treatment (Ref. 144 at Chapter 9).

Some comments also claim that the image is misleading because it suggests that "a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point." Despite experiencing early symptoms for head and neck cancer, some individuals may not be able to seek early cancer screening and detection, resulting in diagnosis only when the disease has become advanced. Factors such as lack of health insurance coverage, lack of financial resources, lack of transportation, and lack of cancer knowledge serve as barriers to cancer screening, resulting in late-stage diagnosis for head and neck cancer (Refs. 143 and 146). As a result, it is not unusual for patients from underserved communities to present at advanced stages for head and neck cancer as depicted in the warning's

image (Ref. 143 at Figure 1a and Ref. 147). Therefore, this image depicts a factually accurate, common visual presentation of the health condition.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking causes head and neck cancer. The accompanying concordant and factually accurate image depicts the head and neck of woman (aged 50-60 years) who has a cancerous growth protruding from her neck below her jawline. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

4. "WARNING: Smoking causes bladder cancer, which can lead to bloody urine."

This required warning consists of the textual warning statement "WARNING: Smoking causes bladder cancer, which can lead to bloody urine" paired with a concordant, factually accurate, photorealistic image depicting bloody urine. The image shows a gloved hand holding a urine specimen cup containing bloody urine resulting from bladder cancer caused by cigarette smoking.

In FDA's final consumer research study, this warning was reported to be new information by 87.2 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking.

Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 57.8 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (66.0 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the "perceived factualness" outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 61) Some comments object to this proposed warning because they assert it is inaccurate and misleading. For example, one comment states that the proposed warning is misleading because it suggests that bloody urine is a more serious health concern than bladder cancer. One comment suggests that, on its own, the image does not convey purely factual

information because a consumer would not be able to determine from the image alone that the liquid depicted is bloody urine or bloody urine resulting from bladder cancer. This comment also asserts that the text and image are not concordant because nothing about the picture indicates that bladder cancer is the subject of the warning.

Some comments suggest that the textual warning statement may be misleading and recommend revisions. For example, one comment suggests changing "can" to "may" or adding a disclaimer that "bladder cancer is not the only cause of bloody urine" and/or "the absence of bloody urine does not mean the absence of bladder cancer." Another comment suggests that the proposed warning may be misleading because it understates the possible negative health consequences and recommends that the textual warning statement say, "Smoking causes bladder cancer, which can lead to removal of part or all of the bladder."

Other comments suggest changes to the image, such as using a different image because the proposed image does not depict a body part or a human face. Another comment recommends making the image of the urine cup more clear by labeling the cup with words such as "urine sample" and darkening the color to a red resembling the color of blood.

Finally, one comment states the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers because the image "appears designed to provoke an emotional reaction of fear or disgust regarding the nature of the depicted liquid."

(Response 61) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking causes bladder cancer, which can lead to bloody urine" is factually accurate, and we decline to make changes to the text. As explained in the proposed rule (see section VII.A.4 of the proposed rule), smoking is a strong causal factor in the development of bladder cancer. Recent research illustrates that even smoking a few cigarettes per day is associated with an increased risk of bladder cancer (Ref. 148), and the CDC estimates that 40 percent of bladder cancer *deaths* (not bladder cancer cases, as one comment asserts) from 2000 through 2004 were attributable to smoking, representing almost 5,000 deaths per year (Ref. 149). Cigarette smoking has repeatedly been identified as the most important risk factor for bladder cancer (Refs. 112–114).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. As stated in the proposed rule, in most cases, blood in the urine (called hematuria) is the first visible sign of bladder cancer (Ref. 150). The Mayo Clinic notes that hematuria results in urine that can be pink, red, or brown/cola-colored (Ref. 151). The current color depicted in the image is factually accurate, and a darker red may lead to confusion as to whether the liquid contains only blood or bloody urine. We also decline to add a qualifying label to the specimen cup that says "URINE SPECIMEN" as the specimen cup with a gloved hand depicts a routine sampling procedure typical in laboratory testing and medical processing of biological samples. Further, the image is already paired with a textual warning statement indicating the cup contains urine. Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows a symptom of the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. We disagree with comments suggesting the warning is misleading or ineffective

because it understates the possible negative health consequences for this health condition; does not depict a body part or face; or does not include information not directly focused on the specific warning, such as the possibility of bladder cancer occurring in the absence of bloody urine or the possibility of other nonsmoking-related causes of bloody urine. FDA also declines to change the image to be a depiction of a body part, in this case a bladder, as research shows that both youth and adults have a limited understanding of what a bladder looks like. For example, in one pilot study with 168 adolescents, only 7.7 percent could correctly label the bladder on a diagram (Ref. 152). This warning is intended to promote greater public understanding of bladder cancer caused by cigarette smoking. As stated in the preceding paragraph, bloody urine is a very common, and, in most cases, the first visible symptom of bladder cancer. The textual warning statement explains that smoking causes bladder cancer, which can lead to bloody urine. The accompanying, concordant, factually accurate image appropriately depicts bloody urine consistent with that seen in cases of bladder cancer caused by smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

5. "WARNING: Smoking during pregnancy stunts fetal growth."

This required warning consists of the textual warning statement "WARNING: Smoking during pregnancy stunts fetal growth" paired with a concordant, factually accurate, photorealistic

image depicting a negative health consequence of smoking during pregnancy: an infant with low birth weight resulting from stunted fetal growth. The image shows a newborn infant on a medical scale, and the digital display on the scale reads four pounds.

In FDA's final consumer research study, this warning was reported to be new information by 40.0 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 66.7 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (83.9 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Participants who viewed this warning showed statistically significant improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3, as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 62) Some comments object to this proposed warning because they assert it is inaccurate and misleading. These comments question the accuracy of the visual depiction of the newborn infant, asserting that fetal growth and birth weight are not the same; the "4.00 lbs." weight displayed in the image represents an extreme example of low birth weight due to smoking; the scale's depiction of "4.00 lbs." conveys very low birth weight commonly associated with premature birth; and FDA has not demonstrated that a birth weight of four pounds is a likely outcome of maternal smoking.

Some comments suggest that the image of an infant on a scale that reads "4.00 lbs." may be difficult to see and therefore recommend increasing the text size of the weight display to help consumers more easily and quickly identify the condition being depicted in the image.

Other comments raise concerns that the infant in the image appears unrealistic and that the low birth weight also relies on viewers/readers to understand what a healthy weight might be. One comment states that the image contains a non-essential element by including the infant's apparent "distress," while another comment notes that "it may not be apparent to all that four pounds is underweight, especially to those with a lower health literacy or to those who are first-time mothers." Other comments recommend changing the image to include an underweight infant next to an average-sized infant or to feature a small infant in an incubator attached to various tubes and lines to better communicate the increased risk of low birth weight.

One comment states the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers because the image is "designed to provoke an instinctive, emotional need in adult viewers to comfort the child."

(Response 62) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking during pregnancy stunts fetal growth" is factually accurate. As stated in the proposed rule, the 2004 Surgeon General's Report concluded that the evidence was sufficient to infer a causal relationship--the highest level of evidence of causal inferences based on the criteria applied in the Surgeon General's Reports--between maternal smoking and fetal growth restriction and preterm delivery (Ref. 138). The 2004 and a subsequent Surgeon General's Report summarized many studies that found a consistent and strong relationship between smoking and reduced birth weight as well as a strong dose-response relationship between smoking intensity and birth weight (Refs. 138 and 153). More recent studies further support the causal relationship between smoking and restricted fetal growth (Refs. 154–157). Further, a recent panel of 57 international leaders in the field of neonatal growth developed a consensus definition of fetal growth restriction using a Delphi method (Ref. 158), and both population-based and customized percentiles for birth weight were accepted in the definition. As such, low birth weight is a strong and important indicator of fetal growth restriction.

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The visual depiction of stunted fetal growth as a newborn weighing four pounds on a scale clearly and accurately represents the negative health consequence of smoking focused in the textual warning statement, since, as described in the preceding paragraph, low birth weight is an important indicator of fetal growth restriction (Ref.

158). FDA disagrees with comments suggesting that four pounds is an "extremely" low birth weight. Epidemiological studies, which show that maternal cigarette smoking increases the risk for very low birth weight infants, define low birth weight as any weight less than 1,500 grams (which is equivalent to about 3 pounds, 4 ounces), therefore four pounds is not an "extremely" low birth weight (Refs. 159 and 160). Further, we disagree that the public will not understand that the infant is low birth weight because of the "4.00 lbs." display on the scale or the infant's appearance. Throughout our iterative process of testing and refining this image, even when study participants did not know the definition of low birth weight, this image was understood as intended. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking during pregnancy stunts fetal growth. The accompanying concordant and factually accurate image depicts a newborn infant with low birth weight due to stunted fetal growth resulting from maternal smoking. As previously stated, the goal of the required warnings is to promote greater public understanding of the negative health consequences of smoking by conveying factual information regarding the causal association between smoking and specific health conditions rather than conveying information about absolute or relative risk of these conditions. Similarly, the goal of this specific warning's image is not to convey that all babies born with stunted fetal growth weigh four pounds, but rather to depict a concordant, factually accurate, common visual presentation of the negative health consequence of smoking described by the textual warning statement.

We decline to make changes to the image to depict elements related to premature birth, such as placing the infant in an incubator or adding tubes. Stunted fetal growth does not necessarily result in premature birth, and premature birth is not the subject of this required warning. The image depicts a low birth weight infant, not necessarily a premature infant who would likely require (and thus be depicted with) additional interventions such as an incubator, oxygen, feeding tube, and additional monitoring (Ref. 161). This image depicts a factually accurate, common visual presentation of the health condition of stunted fetal growth and shows the condition as it is typically experienced.

We disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition (stunted fetal growth) in a realistic and objective format, does not contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response. The inclusion of the weight on the scale further explains that the infant has a low birth weight. We also disagree that the infant in the image is in apparent "distress." Crying among newborns is common and expected in this setting. It is an indicator of healthy lung function so much so that it is included in the widely used APGAR scoring used one and five minutes after birth (Ref. 162).

Finally, with regard to comments suggesting that the image's "4.00 lbs." weight display on the scale may be difficult to see, we agree that this important element of the image may be difficult to view in certain sizes of cigarette packages or advertisements. As a result, for this required warning, we have increased the contrast and size of the weight display in the image to improve image clarity.

6. "WARNING: Smoking can cause heart disease and strokes by clogging arteries."

This required warning consists of the textual warning statement "WARNING: Smoking can cause heart disease and strokes by clogging arteries" paired with a concordant, factually accurate, photorealistic image depicting a patient who recently underwent heart surgery to treat heart disease caused by smoking. The image shows the chest of a man (aged 60-70 years) wearing an open hospital gown. The man has a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring.

In FDA's final consumer research study, this warning was reported to be new information by 52.1 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 49.4 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (85.2 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Participants who viewed this warning showed statistically significant improvements in their health beliefs between Sessions 1 and 2,

but not between Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 63) Some comments object to this proposed warning because they assert it is inaccurate and misleading. One comment suggests that the warning is misleading because it depicts a man who has had recent open-heart surgery, presumably coronary artery bypass grafting (CABG), and the comment provides data showing that in-patient percutaneous coronary interventions (PCIs) are 2.5 times more common than open-heart CABG surgery for treating coronary artery disease (Ref. 163). Another comment asserts that the image depicts a "worst case, rather than representative scenario." One comment states that the textual warning statement and image are not concordant because the text indicates that smoking can lead to heart disease and strokes, but the image, on its own, does not convey that the individual depicted either suffered from heart disease or a stroke. Another comment asserts that the warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers because the depiction of a man with a large, recently-sutured incision "is intended to disgust or shock consumers" or "to make consumers fearful of the prospect of needing to undergo major heart surgery and medical monitoring."

Other comments support the inclusion of this warning in the final rule, emphasizing the strong causal link, based on the conclusions drawn from past Surgeon General's Reports, between cigarette smoking and heart disease and stroke. The comments also reference a 2018 meta-analysis of 141 cohort studies that found that smoking approximately one cigarette per day

carries a much higher risk for developing coronary heart disease and stroke than would be expected if the risk increased in a linear dose-response relationship (Ref. 164).

(Response 63) We disagree with comments suggesting that this warning is inaccurate or misleading. FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking can cause heart disease and strokes by clogging arteries" is factually accurate. As described in the proposed rule (see section VII.A.6 of the proposed rule), coronary heart disease--often simply called heart disease--is a disorder of the blood vessels of the heart that can lead to a heart attack. Stroke occurs when blood supply to part of the brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients (Ref. 165). Atherosclerosis, or clogged arteries, is a disease in which plaque builds up inside the arteries that carry oxygen-rich blood to the heart and other parts of the body and can lead to heart attack and stroke through thrombosis, or blockage of the arteries (Refs. 3 and 165). Most coronary heart disease involves atherosclerosis, or clogged arteries. Also as described in the proposed rule, Surgeon General's Reports since the 1970s have concluded that smoking is causally related to heart disease and stroke (Refs. 138 and 166), and smoking is consistently identified as a major risk factor for heart disease and stroke (Refs. 35, 115, 116, and 167). Across many studies over time, a clear dose-response relationship has been established with smoking more cigarettes and smoking for a longer time linked to greater risk of heart disease and stroke. More recent evidence demonstrates that even a very low frequency of smoking (i.e., even as few as one cigarette per day) has a measurable increase in the risk for cardiovascular disease (CVD) (Ref. 164).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image shows the chest of a man (aged 60-70 years) wearing an open hospital gown. The man has a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring. As one comment notes, while inpatient discharges for CABG surgery have decreased over time, in 2014 there were still over 350,000 individuals who underwent the procedure as a consequence of coronary artery disease (Ref. 163). The appropriate use criteria and decision for treatment approaches is based on many clinical factors, with both CABG (as depicted) and PCI commonly used (Ref. 168). Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking can cause heart disease and strokes by clogging arteries. The accompanying concordant and factually accurate image depicts a patient who received treatment for heart disease caused by clogged arteries due to smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

7. "WARNING: Smoking causes COPD, a lung disease that can be fatal." [image of man with oxygen tank]

This required warning consists of the textual warning statement "WARNING: Smoking causes COPD, a lung disease that can be fatal" paired with a concordant, factually accurate, photorealistic image depicting a man receiving oxygen support because he has COPD caused by cigarette smoking. The image shows the head and neck of a man (aged 50-60 years) who has a nasal canula under his nose supplying oxygen; the oxygen tank can be seen behind his left shoulder.

In FDA's final consumer research study, this warning was reported to be new information by 35.7 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 57.8 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (83.8 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Despite the strong results on nearly all other measures included in the study, this warning did not show statistically significant

improvements in health beliefs between either Sessions 1 and 2 or between Sessions 1 and 3 over the changes in participants who viewed the Surgeon General's warnings, which is not surprising given the relatively brief exposure to the warning. Full details of the results for this warning are available in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 64) Multiple comments provide data supporting this warning, since smoking is the leading cause of COPD. One comment emphasizes that a warning depicting COPD--either with an image of a diseased lung or the need for oxygen as a result of COPD--would be "more impactful than a simple statement that 'nicotine is addictive' or 'smoking is dangerous to your health.'" The same comment notes that COPD is the fourth leading cause of death, is one of the costliest conditions with respect to hospital readmissions, and the medical profession witnesses "the devastating consequences of tobacco use among COPD patients every day."

(Response 64) We agree that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 65) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment states that the image does not, on its own, convey purely factual information because "[n]o reasonable consumer would be able to determine from the image alone that the man depicted suffers from COPD." Rather, the comment suggests, all the image conveys is that the man needs oxygen support. Another comment confirms that long-term oxygen therapy, delivered through a nasal canula, as depicted in the

proposed warning, is one of several treatments for COPD (Ref. 169); however, the comment asserts that the proposed warning depicts a "worst case scenario" without discussion of the proportion of smokers developing COPD who will require long-term oxygen therapy or home oxygen. Finally, one comment states that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers, because the image "appears designed to make consumers fearful of the prospect of needing to rely upon an oxygen tank to survive."

(Response 65) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking causes COPD, a lung disease that can be fatal" is factually accurate. As stated in the proposed rule, COPD includes the diseases emphysema and chronic bronchitis. The 1964 Surgeon General's Report concluded that smoking is a primary cause of chronic bronchitis, and subsequent reports summarized additional evidence to conclude, in the 2004 Surgeon General's Report--at the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--that the evidence is sufficient to infer a causal relationship between active smoking and COPD morbidity and mortality (Refs. 138, 170, and 171). The 2014 Surgeon General's Report reinforced and extended this evidence to discuss the relationship between smoking and COPD mortality (Ref. 3). The 2014 Surgeon General's Report concluded that the evidence is sufficient to infer--once again, the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--that smoking is in fact the dominant cause of COPD in the United States (Ref. 3). The

mortality risk from COPD for current smokers compared to never smokers was 25.61 times higher for men and 22.35 times higher for women, according to 50-year trends published in the *New England Journal of Medicine* (Ref. 172). There are about 128,000 COPD deaths in the United States each year, of which 101,000 (79 percent) are attributable to smoking (Ref. 3).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. Oxygen therapy is not rare and is recommended for symptom relief and prolonging life, and many patients with COPD can use oxygen for several years. Oxygen therapy may be used with patients with COPD who have symptoms of both severe and moderate hypoxemia (i.e., abnormally low level of oxygen in the blood) to improve survival and quality of life (Refs. 173 and 174). Each year, more than 1.5 million adults in the United States use supplemental oxygen therapy (Ref. 175), including those with COPD. For example, among Medicare beneficiaries with COPD in 2010, 40.5 percent received oxygen therapy and 18.5 percent received sustained oxygen therapy (Ref. 176). Quality of life can be improved for adults with COPD through the regular use of long-term oxygen therapy (Ref. 177). Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state and treatment for the disease as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking causes COPD, a fatal lung disease. Including the qualifying clause stating that COPD is a fatal lung disease further explains and provides important information of this negative health consequence of smoking. The accompanying concordant and factually accurate image depicts a man with COPD receiving oxygen treatment. Because the required warning contains the textual warning statement and

image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

(Comment 66) One comment asserts that FDA has not provided any scientific basis for requiring two cigarette health warnings on COPD (identical textual warning statements paired with two different images) when only one warning was proposed for all other health conditions.

(Response 66) As noted in the proposed rule (see section VI.B of the proposed rule), based on the results of FDA's first consumer research study (Ref. 12), FDA selected a total of 15 textual warning statements for testing in the final consumer research study (Ref. 17). However, when each of the textual warning statements were paired with concordant photorealistic images, two of the textual warning statements ("WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" and "WARNING: Smoking causes COPD, a lung disease that can be fatal") shared similar concordant images ("diseased lungs"). To preserve the option of potentially requiring both textual warning statements but without using two similar images, FDA paired an additional concordant image ("man with oxygen tank") with the COPD textual warning statement for further testing. Therefore, FDA tested a total of 16 text-and-image pairings in the final quantitative consumer research study. Results from that study show that both images ("diseased lungs" and "man with oxygen tank"), paired with the same COPD textual warning statement, performed well across the outcomes measured, indicating that either pairing would advance the Government's interest in promoting greater public understanding of the negative health

consequences of cigarette smoking (Ref. 17). We are therefore finalizing this cigarette health warning--and not the COPD warning with the image of diseased lungs--to avoid having two identical textual warning statements about COPD and to avoid having two similar, concordant images of diseased lungs paired with different textual warning statements.

8. "WARNING: Smoking reduces blood flow, which can cause erectile dysfunction."

This required warning consists of the textual warning statement "WARNING: Smoking reduces blood flow, which can cause erectile dysfunction" paired with a concordant, factually accurate, photorealistic image depicting a man who is experiencing erectile dysfunction caused by smoking. The image shows a man (aged 50-60 years) sitting on the edge of a bed and leaning forward, with one elbow resting on each knee. The man's head is tilted down, with his forehead pressed into the knuckles of his right hand. Behind him on the bed, his female partner looks off in another direction.

In FDA's final consumer research study, this warning was reported to be new information by 78.8 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health

effects of smoking. The warning was correctly recalled by 61.4 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (72.4 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition. Participants who viewed this warning showed statistically significant improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3, as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 67) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment asserts that the image, on its own, does not convey purely factual information, because "it does not provide *any* health information" (emphasis added) and "in no way illuminates how smoking could cause erectile dysfunction." The comment further states that the warning is misleading because it emphasizes a chronic, non-fatal condition rather than other conditions with high mortality rates. The comment also states that the warning "focuses on erectile dysfunction while omitting mention of more common side effects of low blood flow, such as numbness or weakness in the legs." Finally, the comment states that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers, because the image "is clearly designed to generate embarrassment and shame in viewers regarding the sensitive topic of sexual intimacy."

Another comment acknowledges that some health conditions are more difficult to depict than others. In the case of this warning, the comment explains that, while "literal depictions" of the health conditions are generally preferable, the use of a more "symbolic" image is "justified" for this health condition and warning.

(Response 67) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking reduces blood flow, which can cause erectile dysfunction" is factually accurate. As discussed in the proposed rule and in reports of the Surgeon General, there is strong support that smoking causes erectile dysfunction. The 2014 Surgeon General's Report concluded that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and erectile dysfunction (Ref. 3). A recent meta-analysis of studies that included 50,360 participants found that smoking more cigarettes and smoking for a longer time were associated with increased erectile dysfunction risk (Ref. 178). Smokers have been found to have a 40 percent increased risk of erectile dysfunction in studies such as the Health Professionals Follow-up Study and the Olmsted County Study of Urinary Symptoms and Health Status (Refs. 179 and 180). Erectile dysfunction is likely under-reported in epidemiological studies; therefore, the effect estimates observed in studies are likely an underestimate. Finally, FDA disagrees with the comment suggesting only conditions with high mortality rates will directly advance the Government's interest. The substantial public health burden of cigarette smoking includes individuals with chronic, non-fatal diseases, and the

Government has a substantial interest in improving public understanding about the negative health consequences of smoking that encompass health conditions beyond those with the highest mortality rates.

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The man in the image is aged 50-60 years, which is an appropriate age range for men experiencing erectile dysfunction caused by cigarette smoking (Ref. 181). Also, as one comment notes, some health conditions are more difficult to depict literally and therefore depicting the "situational context" is justified. In the case of this required warning, FDA included additional realistic and contextual details (e.g., the man's posture, state of undress, bedroom setting, intimate partner) to depict the health condition.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. This warning is intended to promote greater public understanding that cigarette smoking reduces blood flow and can cause erectile dysfunction. The textual statement explains that smoking reduces blood flow, which can cause erectile dysfunction, thereby describing the mechanism through which smoking can cause this health effect. The accompanying concordant and factually accurate image depicts a man experiencing erectile dysfunction caused by smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and appropriately contextual format, does not contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

9. "WARNING: Smoking reduces blood flow to the limbs, which can require amputation."

This required warning consists of the textual warning statement "WARNING: Smoking reduces blood flow to the limbs, which can require amputation" paired with a concordant, factually accurate, photorealistic image depicting the feet of a person who had several toes amputated due to tissue damage resulting from peripheral vascular disease (PVD) caused by cigarette smoking.

In FDA's final consumer research study, this warning was reported to be new information by 74.7 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 73.8 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (76.7 percent) perceived the warning to be factual, a result that was significantly lower than the control condition. Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and

Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning are available in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 68) Some comments object to this proposed warning because they assert it is inaccurate and misleading in a number of respects. One comment states that the warning's image does not convey purely factual information because "[n]o reasonable consumer would be able to determine from the image alone" that the individual's amputated toes were due to tissue damage from PVD. The comment asserts that "the text gives meaning to a disturbing image, rather than the other way around." Two comments question the accuracy of the image, asserting that it depicts Buerger's disease, "a condition that could affect, at most, one in 1,000 smokers." One comment suggests the proposed warning is misleading, because "only a small proportion of patients" with PVD require amputation, and the prevalence of PVD in patients who have no symptoms is high.

Another comment states that the text and image are not concordant because "[n]othing about the picture indicates that the amputation resulted from reduced blood flow, let alone that the reduced blood flow reflects peripheral vascular disease." Instead, the comment claims, the "mismatch" between the text and the image "adds to the fear and confusion a consumer would experience when viewing the warning." Finally, the comment states that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers, because the image "is disturbing and unsightly and is clearly designed to provoke

either disgust at the sight of the image, fear at the prospect of undergoing an amputation, or both."

(Response 68) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking reduces blood flow to the limbs, which can require amputation" is factually accurate. As discussed in the proposed rule, smoking is known to affect cardiovascular health in a number of ways. Smoking can cause peripheral arterial disease (PAD), also known as PVD, a health condition that causes arteries to narrow, which limits the flow of oxygen-rich blood to organs and other parts of the body, including arteries in the legs (Ref. 182). Complications of reduced blood flow to the limbs include amputation or loss of limbs due to tissue damage caused by poor oxygen supply. Numerous Surgeon General's Reports have summarized the strong causal evidence between smoking and PAD/PVD and concluded that cigarette smoking is the most powerful risk factor predisposing individuals to this condition (Refs. 3 and 183). Moreover, also as discussed in the proposed rule (see section VII.A.10 of the proposed rule), the population health burden of PAD/PVD is high: overall prevalence of PAD/PVD was found to be 13.5 percent in 2012 in the Atherosclerosis Risk in Communities study (Ref. 184); a meta-analysis found that the risk of the condition was 2.71 times greater for current smokers and 1.67 times greater for former smokers compared to never smokers (Ref. 185); and the 2014 Surgeon General's Report showed that risk estimates have increased over time (Ref. 3).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image shows a complication resulting from this health condition, namely, toes that have been amputated due to tissue damage caused by reduced blood flow due to PAD/PVD. As discussed in the proposed rule, among people with critical limb ischemia (i.e., a severe blockage of the arteries that greatly reduces blood flow due to PAD/PVD), 25 percent have amputations each year (Ref. 186). Another article estimates that "over 90% of all limb amputations in the Western world occur as a direct or indirect consequence" of PAD/PVD (Ref. 187). Because the warning's image depicts a person who had several toes amputated due to tissue damage resulting from PAD/PVD caused by cigarette smoking of undefined etiology, the image is consistent with PAD/PVD and is not specific to Buerger's disease, as one comment suggested (see Refs. 188 and 189). Therefore, this image depicts a factually accurate, common visual presentation of the outcome of the health condition and shows the disease state as it may be experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking reduces blood flow to the limbs, which can require amputation. The accompanying concordant and factually accurate image depicts the feet of a person who has had several toes amputated due to tissue damage resulting from reduced blood flow to the limbs caused by cigarette smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not

contain additional unnecessary details (e.g., background setting, surgical instruments used to remove the toes), and does not contain any elements intended to evoke a negative emotional response.

10. "WARNING: Smoking causes type 2 diabetes, which raises blood sugar."

This required warning consists of the textual warning statement "WARNING: Smoking causes type 2 diabetes, which raises blood sugar" paired with a concordant, factually accurate, photorealistic image depicting a personal glucometer device being used to measure the blood glucose level of a person with type 2 diabetes caused by cigarette smoking. The digital display reading of 175 mg/dL and a notation on the glucometer indicate a high blood sugar level.

In FDA's final consumer research study, this warning was reported to be new information by 87.2 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 62.3 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (64.0 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the "perceived factualness" outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 69) Multiple comments support the inclusion of this warning in the final rule and provide additional epidemiological and other scientific data to support the text and image components, including a scientific review that concluded that cigarette smoking increases the risk for type 2 diabetes incidence (Ref. 190).

(Response 69) FDA appreciates the submission of additional scientific and other support for the inclusion of this warning focused on smoking causing type 2 diabetes. We agree that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 70) Some comments recommend FDA consider modifying the textual warning statement language or adding a separate warning related to smoking's causal link to type 2 diabetes. For example, suggestions from comments include "Smoking causes type 2 diabetes, which can cause kidney disease or failure" and "Smokers with diabetes (and people with diabetes exposed to secondhand smoke) have a heightened risk of CVD, premature death, microvascular complications, and worse glycemic control when compared with nonsmokers." Some comments

recommend that the textual warning statement convey the "gravity" of the disease or the serious complications of potentially greater concern to consumers without diagnosed diabetes (e.g., CVD, kidney disease, blindness, blurry vision, numbness in the hands and feet, amputation).

(Response 70) While FDA agrees that there are other serious complications resulting from type 2 diabetes, we decline to make the suggested changes. The textual warning statement is factually accurate and is supported by strong epidemiological evidence that confirms the appropriate use of the causal language as written. The phrasing is appropriate, accurate, and consistent with the other required warnings, and it has performed well in FDA's consumer research studies, both on its own (in the first consumer research study) and when paired with a concordant photorealistic image (in the final consumer research study). The results of our rigorous science-based, iterative research process indicate that this warning will advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking.

(Comment 71) One comment recommends FDA remove numeric digital display readings from the glucometer portion of the image because "desired blood glucose targets vary among individuals with diabetes" and including a specific numeric value in the image "could be confusing for people with diabetes." The comment raises concern that individuals could misconstrue such a value (i.e., 175) as indicative of the appropriate glycemic target for their own care. Another comment suggests blood sugar levels may be less meaningful to some people.

(Response 71) FDA declines to make the suggested change. As the comment notes, there may be a range of desired blood glucose targets for different individuals; however, type 2 diabetes is defined as a fasting blood sugar greater than 126 mg/dL (Ref. 191), which is clearly and accurately depicted in this image. Further, the required warnings are not intended to provide

individual diagnostic medical information or encourage individuals to seek treatment, but rather to promote greater public understanding of the negative health consequences of cigarette smoking--in this case, that smoking causes type 2 diabetes, which raises blood sugar.

(Comment 72) A comment from a group of research scientists shares findings from a recent study of 443 U.S. adults testing images for a sugar-sweetened beverage warning about type 2 diabetes. The comment states that an image similar to the one proposed here was the most common choice (selected by 34 percent of participants) of an image that "best represented" type 2 diabetes.

(Response 72) FDA appreciates the submission of this study; however, the study does not appear to be published and few details were submitted about the study methods or full results.

(Comment 73) Some comments object to this proposed warning, because they assert it is inaccurate and misleading in a number of respects. One comment states that the image, on its own, does not convey purely factual information, because "the average consumer is unlikely to be aware of the meaning of the '175' reading on the glucometer (or even to recognize the device as a glucometer)." For that reason, the comment states that the text and image are not concordant because the image "does not relate to diabetes without knowledge of additional information not depicted." Another comment suggests that the image is not accurate because a blood sugar level of 175 mg/dL is "well in excess of the minimal threshold for diabetes."

One comment states that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers, because the image "appears designed to provoke the emotional reaction of fear or disgust that many experience when faced with the prospect of a medical procedure involving needles and drawing blood." Moreover, the comment claims that the depiction of blood being drawn "threatens to cause an emotional or fearful

reaction in many consumers" and "is not necessary" to inform consumers regarding the risk of type 2 diabetes.

(Response 73) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking causes type 2 diabetes, which raises blood sugar" is factually accurate. This statement is supported by strong epidemiological evidence that confirms the appropriate use of the causal language as written, as other comments note. The phrasing is also appropriate, accurate, and consistent with the other required warnings. The 2014 Surgeon General's Report concluded that: (1) the evidence is sufficient to infer--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--that cigarette smoking is a cause of type 2 diabetes; (2) the risk of developing diabetes is 30 to 40 percent higher for active smokers than nonsmokers; and (3) there is a relationship between increased number of cigarettes smoked and increased risk of developing diabetes (Ref. 3). Across the 25 studies included in the 2014 Surgeon General's Report's updated summary, the associations were strong and consistent and were found in many subgroups, and these results have been replicated in many different study populations and study locations. Moreover, additional scientific support for this causal link was submitted in other comments (see, e.g., Ref. 190).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image depicts a common action taken by people with type 2 diabetes: glucose monitoring. According to the American Diabetes

Association, "[f]or many people with diabetes, glucose monitoring is key for the achievement of glycemic targets" and is "an integral component of effective therapy of patients taking insulin" (Refs. 192 and 193). Frequent testing of blood glucose is a reality for people with diabetes, and the image of a personal glucometer device being used to measure the blood glucose level is a common depiction of diabetes. Thus, there is support that an image of routine glucose monitoring is representative of type 2 diabetes in other contexts.

With regard to the numerical display, we disagree that the image depicting a blood sugar level of 175 mg/dL is inaccurate. While diabetes is defined as a fasting blood sugar greater than 126 mg/dL, there are more complex criteria needed for an accurate diagnosis of type 2 diabetes (Ref. 194). A glucose level of 175 mg/dL is consistent with the American Diabetes Association guidelines, which recommend patients target peak post-meal blood glucose levels of <180 mg/dL to help lower average glycemic levels and improve glycemic control (Ref. 192). Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking can cause type 2 diabetes, which raises blood sugar. The accompanying concordant and factually accurate image depicts a personal glucometer device being used to measure the blood glucose level of a person with type 2 diabetes caused by cigarette smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not

contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

11. "WARNING: Smoking causes cataracts, which can lead to blindness."

This required warning consists of the textual warning statement "WARNING: Smoking causes cataracts, which can lead to blindness" paired with a concordant, factually accurate, photorealistic image depicting a closeup of the face of a man (aged 65 years or older) who has a cataract caused by cigarette smoking. The man's right pupil is covered by a large cataract.

In FDA's final consumer research study, this warning was reported to be new information by 88.7 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of "new information" and "self-reported learning" are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p < 0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 53.0 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (65.5 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion

of the "perceived factualness" outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 74) Multiple comments strongly support the inclusion of this proposed warning in the final rule and provide additional epidemiological and other scientific data to support the text and image components of this warning.

(Response 74) FDA agrees with the comments that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 75) Some comments recommend that, since women generally have a longer life expectancy than men in the United States and are therefore more likely to develop age-related eye problems, FDA should consider changing the image to one of a woman with a cataract.

(Response 75) We decline to make this revision. The warning is factually accurate and appropriate for the purpose of this rule, which is to promote greater public understanding of the negative health consequences of cigarette smoking. It is not feasible, nor is it our intention, for a single warning to convey all the information that may be related to a particular health condition, such as populations with the highest prevalence of a disease, projected incidence rates, relative risk, mortality rates, or disparities in affected populations. Rather, this required warning presents

a factually accurate visual depiction of the negative health condition that is concordant with the paired textual warning statement.

(Comment 76) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment states that the image does not convey purely factual information, because the image, on its own and without the accompanying text, "simply shows a man with one eye differently colored than the other" and "[t]here is no reason for a consumer to know that the depicted eye-color variation represents 'a large cataract.'" The comment further states that the warning emphasizes a chronic, non-fatal condition, rather than other conditions with high mortality rates. The comment also states that the warning emphasizes a condition (blindness) that occurs in only a small minority of cataracts.

Another comment states that the image is "not a reasonable depiction of persons with cataracts" because the cataract "would have been treated surgically long before it got to this stage." In addition, the same comment asserts that the image "misleadingly" makes the cataract look like a cosmetic problem, "when in reality, '[t]he vast majority of patients who undergo cataract surgery in the [United States] have cataracts that are undetectable by the unaided human eye.'" Another comment repeats these objections, and one comment notes that cataracts can be treated with "highly successful cataract surgery and do not result in permanent visual loss."

One comment asserts that the text and image are not concordant, because the text indicates that smoking can lead to blindness "[y]et the picture does not clearly indicate that the individual depicted is blind."

Finally, one comment states that the proposed warning "seeks to advance FDA's anti-smoking message" by evoking an emotional response in consumers, because the image "is

discomforting and appears designed to shock the viewer or generate fear at the prospect of experiencing the condition in the image."

(Response 76) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement "WARNING: Smoking causes cataracts, which can lead to blindness" is factually accurate. As discussed in the proposed rule, the 2004 Surgeon General's Report on cigarette smoking concluded that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and cataracts in the lens of the eye (referred to as nuclear cataracts) (Ref. 138). Authors have continued to identify smoking as a major causal risk factor in the development and progression of cataracts (Refs. 195–197). Studies of smoking cessation and risk of cataracts has affirmed that risk decreases, but is not equivalent to never smokers, upon elimination of the exposures of tobacco smoke (Ref. 198).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image depicts a close-up of the face of a man aged 65 years or older, which is an appropriate age range for this condition. As stated in the proposed rule (see section VII.A.13 of the proposed rule), prevalence of cataracts among U.S. adults aged 40 years and older in 2010 was estimated to be 17.1 percent by the National Eye Institute (Ref. 199). A study of people affected by cataracts worldwide estimated that in 2010, there were more than 400,000 (range: 240,000 to 850,000) people with cataracts in North

America, of whom 13.0 percent (95 percent, CI: 7.8. 19.5) were blind as a result of that cataract (Ref. 200).

FDA disagrees with the comment suggesting that only depictions of conditions with high mortality rates will directly advance Government's interest. As stated in section V.A, the substantial public health burden of cigarette smoking includes individuals with chronic, non-fatal diseases, and therefore FDA has an opportunity to improve public understanding about the negative health consequences of smoking that encompass health conditions beyond those with the highest mortality rates.

FDA also disagrees with the comment suggesting that the image is not a reasonable depiction because persons would have been treated surgically before advancing to the stage depicted. Research has shown that individuals from underserved populations may face barriers to receiving cataract surgery due to factors such as lack of access to medical care, lack of insurance coverage, lack of financial resources, and lack of transportation (Refs. 201 and 202). Thus, it is factually accurate and not uncommon for individuals to experience advanced cataracts as depicted in the image.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking causes cataracts, which can lead to blindness. The accompanying concordant and factually accurate image depicts a man with a large cataract caused by smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not

contain additional unnecessary details (e.g., background setting), and does not contain any elements intended to evoke a negative emotional response.

C. Non-selected Cigarette Health Warnings

This section discusses the two proposed warnings that FDA is not selecting. In the proposed rule, we indicated that we would make these decisions following our review of public comments and after weighing additional scientific, legal, and policy considerations. In the following paragraphs, FDA briefly describes the study outcomes for each warning and the comments we received.

1. "WARNING: Smoking causes COPD, a lung disease that can be fatal [image of diseased lungs]."

As explained in section VI of the proposed rule, FDA included two textual warning statements ("WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" and "WARNING: Smoking causes COPD, a lung disease that is fatal") that were each paired with similar concordant images of diseased lungs. The proposed textual warning statement ("Warning: Smoking causes COPD, a lung disease that can be fatal") paired with the image of diseased lungs showed strong results in FDA's final consumer research study, showing statistically significant higher ratings across nearly all outcomes. The warning was perceived to be factual by a majority of participants, a result that was not statistically different from the Surgeon General's warnings (i.e., the control condition). Participants who viewed this warning showed improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3. To avoid having two identical textual warning statements about COPD and to avoid having two similar, concordant images of diseased lungs paired with different textual warning statements, FDA is not finalizing this cigarette health warning. FDA concludes that having only

one required warning statement on COPD reflects the Congressional intent of representing a diverse set of health conditions and furthers the Government's interest in promoting public understanding of the negative health consequences of smoking. In the following paragraphs, FDA briefly describes and responds to the comments received on this proposed warning.

(Comment 77) FDA received numerous comments generally supporting all of the proposed warnings, including this proposed warning. FDA received some comments supporting both proposed warnings related to COPD stating smoking is the number one leading cause of COPD. Other comments, however, oppose this proposed warning, stating that the proposed rule contains no discussion regarding the relationship between smoking and the image in the proposed rule; the warning fails to convey the relationship between cigarette use topography and the depicted image; and that such lung pigmentation is unlikely to occur except after "many years" of "heavy" smoking. Another comment recommends FDA consider using only one of the two similar images of diseased lungs because studies show that rotating warnings and using a variety of topics and images can improve the effectiveness of warnings.

(Response 77) Although we disagree with the comments that suggest the proposed warning did not adequately convey the relationship between cigarette use and the depicted image, we have elected not to finalize this warning. As we recognized in section VI of the proposed rule, and as at least one comment suggests, it is important that the required warnings use a variety of topics and images. As previously noted, FDA has determined that including one required warning on COPD is consistent with Congressional intent of representing a diverse set of conditions and also advances the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

2. "WARNING: Smoking causes age-related macular degeneration, which can lead to blindness."

This proposed textual warning statement on age-related macular degeneration (AMD) is paired with an image of an older man (aged 65 years or older) who is receiving an injection in his right eye to prevent additional vessel growth. This proposed textual warning statement did well in FDA's final consumer research study, showing statistically significant higher ratings across all outcomes except perceived factualness. However, FDA is not finalizing this cigarette health warning because FDA has determined that having only one required warning statement related to blindness reflects the Congressional intent of representing a diverse set of health conditions and furthers the Government's interest in promoting public understanding of the negative health consequences of smoking. In the following paragraphs, FDA briefly describes and responds to the comments received on this proposed warning.

(Comment 78) As with the other proposed warnings, this warning received general support. Several comments (including from state societies of optometric physicians and a national professional medical association for optometric medicine) support the warning but recommend revisions, including that the image should depict the effects of AMD rather than the treatment of the disease, e.g., by using one of the commonly cited images produced by the National Eye Institute depicting a blurred image of a child (as seen from the vantage point of a person with AMD). Some comments also recommend that we change the proposed image of a black man with AMD to a Hispanic woman with AMD, citing data from the National Eye Institute. Other comments oppose this proposed warning, stating that FDA did not assess whether consumers viewing the proposed warning understood the absolute risk of macular degeneration in general, or among smokers. One comment notes that the depiction of treatment

of macular degeneration is not accurate as the needle depicted is thicker than one that would actually be used to treat macular degeneration and would not ordinarily be inserted in the center of the eye, as depicted.

(Response 78) We agree with the comments that generally support the inclusion of a cigarette health warning that addresses blindness. Although this proposed warning showed strong results in the final consumer research study, after considering the comments, we have elected not to finalize it. As previously noted, FDA has determined that including one required warning on blindness is consistent with Congressional intent of representing a diverse set of conditions and also advances the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

VIII. Alternatives

In the proposed rule, FDA invited proposals for alternative text and images and requested that any proposals include scientific information supporting that the proposed alternative would, in fact, promote greater public understanding of the negative health consequences of smoking. In response, FDA received a number of comments suggesting text or image edits, and some suggestions for additional required warnings or other changes. As we explain in section VII, we are finalizing 11 of the 13 proposed required warnings after reviewing all the public comments and weighing additional scientific, legal, and policy considerations. We also address in section VII suggestions specific to those required warnings. In the following paragraphs, FDA summarizes other comments we received that suggest additional required warnings or general additions or changes we might consider.

(Comment 79) FDA received several comments suggesting that the required warnings provide additional textual information, such as information on tobacco cessation or Quitlines;

information on the positive outcomes of quitting smoking (or warnings using "gain-framed" phrasing); or information on the harmful effects of menthol. Other comments suggest specific warnings FDA should require, in addition to or in place of the required warnings proposed by FDA. For example, one comment suggests that there be a required warning addressing the dangers of tobacco smoke pollution or secondhand smoke, citing information from the CDC (Ref. 203). The comment suggests that the warning state, "WARNING: Secondhand smoke can cause heart disease and strokes by clogging arteries." This comment also suggests adding a warning on breast cancer that states, "WARNING: Smoking can cause breast cancer, especially in younger women." To target young individuals who are image conscious, another comment suggests developing a warning related to how smoking will harm appearance, such as "WARNING: Using this product will make you look old and wrinkled. Smoking speeds up the aging of skin and causes premature sagging."

Other comments recommend including additional image elements to the proposed required warnings. For example, one comment suggests use of a hazard alert triangle symbol (i.e., a yellow triangle with an exclamation point in the middle), or the United Nations Globally Harmonized System cancer/chronic health hazard symbol, which is already mandated by the Occupational Safety and Health Administration for chemicals. This comment recommends displaying one or both of these symbols beside the text "WARNING" "both to assist non-English speakers and to make the message more noticeable." Another comment recommends that FDA change the background of the warnings to the same yellow used on highway warning signs (e.g., similar to a school zone warning sign), suggesting this would increase the warnings' visibility and strengthen their effectiveness and would more clearly transmit that the required warning is a "warning." One comment suggests FDA adopt a regulation requiring plain packaging of

cigarettes with warning labels to eliminate tobacco packaging as a form of advertising and promotion.

Several of the comments frame their suggestions as topics for future rulemakings, with some comments encouraging FDA to begin the process of developing additional cigarette health warnings, in part, as a means to address the concerns of wear out, overexposure, or loss of effectiveness.

(Response 79) As we discuss in section VII, after carefully reviewing the different suggestions that were made, as well as weighing scientific, legal, and policy considerations, FDA is finalizing 11 of the 13 warnings that were included in the proposed rule. In general, no scientific information was submitted to demonstrate that these additional suggested warnings or other suggested changes would improve consumer understanding of the negative health consequences of smoking; not all the suggested health consequences meet FDA's standard for verifying the level of causal inference from the reports of the Surgeon General; and some health topics are already covered by the required warnings. We also note that although one of the nine Tobacco Control Act statements FDA tested in the first consumer research study ("WARNING: Quitting smoking now greatly reduces serious risks to your health"), is a gain-framed message (i.e., one that focuses on the positive outcome of taking an action), this statement is not aligned with this rule's approach to promoting greater public understanding of the negative health consequences of cigarette smoking because its focus is not on understanding of the negative health consequences of smoking. FDA also recognizes that several of these comments suggested that their recommended warnings could require additional notice and another opportunity for public comment.

We discuss concerns related to wear out (or overexposure) in section IX. As explained there, the requirements in § 1141.10(g), namely that required warnings on packages be randomly and equally displayed and distributed and required warnings in advertisements be rotated quarterly in alternating sequence in accordance with an FDA approved plan, will help address the concerns of overexposure and loss of effectiveness over time. Additionally, FDA has authority under section 202(b) of the Tobacco Control Act to conduct future rulemakings as needed to address these concerns if such a change would promote greater public understanding of the risks associated with the use of tobacco products.

IX. Description of the Final Rule--Part 1141

A. Overview of the Final Rule

In the proposed rule, FDA explained that this rule will replace part 1141 in Title 21 of the Code of Federal Regulations. The final rule requires new warnings on cigarette packages and advertisements. Although the proposed rule included 13 required warnings, following our review of the comments on the proposed rule and other considerations, as described in section VII, FDA is finalizing 11 required warnings. The required warnings comprise 11 textual warning statements each accompanied by a color graphic depicting the negative health consequences of smoking. FDA also made clarifications related to the materials that we are incorporating by reference.

The final rule is authorized by section 4 of the FCLAA, as amended by sections 201 and 202 of the Tobacco Control Act, which directs FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany textual warning statements, and permits FDA to adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required

under the FD&C Act, if such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In accordance with section 4 of the FCLAA, the final rule directs that a required warning must comprise at least the top 50 percent of the front and rear panels of cigarette packages and at least the top 20 percent of the area of advertisements. The final rule also provides that the required warnings in packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with an FDA-approved plan. The required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with an FDA-approved plan. Each tobacco product manufacturer must maintain a copy of the plan and make it available for inspection and copying by officers or employees duly designated by the Secretary. The FDA-approved plan must be retained while in effect and the plan must be retained for a period of not less than 4 years from the date it was last in effect. The required warnings will promote greater public understanding of the negative health consequences of cigarette smoking. The following paragraphs briefly describe the final rule, as well as the comments FDA received and our responses to those comments.

B. Description of Final Regulations and Comments

1. Section 1141.1--Scope

This section establishes that the requirements apply to manufacturers, distributors, and retailers of cigarettes except as described in this section. First, manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States would not be subject to the rule (proposed § 1141.1(b)). Second, we proposed

in § 1141.1(c) that retailers would not be in violation for cigarette packaging that: (1) contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or part 1141. However, this proposed subsection would require that a retailer ensure that all cigarette packages they display or sell contain a warning that is unobscured by stickers, sleeves, or other materials on the packages, for example. Third, we proposed that under § 1141.1(d), the advertisement requirements in proposed § 1141.10 would apply to a retailer only if the retailer is responsible for or directs the warnings for advertising. Retailers would be liable if they display, in a location open to the public, an advertisement that does not contain a warning (proposed § 1141.1(d)). Proposed § 1141.1(d) provided, however, that retailers would be in violation of the FCLAA and this proposed part if they alter cigarette advertising in a way that is material to the requirements, for example, by obscuring or covering up the warning (e.g., blocking with a sticker or marker), shrinking the warning, or using a sleeve to cover the warning.

We received some comments suggesting a different scope, and we summarize those comments and our responses in the following paragraphs. We are finalizing this section without change.

(Comment 80) Many comments suggest that the rule should apply to all nicotine and tobacco products or suggest that FDA implement similar warning labels on non-cigarette tobacco products, such as cigars, smokeless tobacco, and electronic nicotine device systems, in part, because educating the public about the risks of these products would also serve a legitimate public interest.

(Response 80) The FCLAA explicitly applies to cigarettes, and thus it is beyond the scope of this rulemaking to address products other than cigarettes.

(Comment 81) FDA received comments suggesting that the rule should not apply to heated tobacco sticks and, in particular, the heated tobacco product, Heatsticks, used with the IQOS holder. The comments state that that the proposed rule did not explain how the warnings, images, or factual record apply to non-combustible cigarettes or how the required warnings would be accurate and non-misleading applied to these products. Although the comments acknowledge that the product falls within the FCLAA definition of "cigarette," the comments suggest the rule's scope should be limited to combustible cigarettes.

The comments highlight that FDA's communications indicate not all products classified as cigarettes under the FCLAA present the same risk profile, such as language that "the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke" (Ref. 145). Thus, the comments suggest that applying the required warnings to IQOS and Heatsticks would "undercut [FDA's] important health objectives."

One comment argues that any rule that does not exempt Heatsticks would violate the APA for three reasons: (1) FDA did not carry its burden of showing the evidence supporting the required warnings applies to Heatsticks (rather FDA's justifications in the proposed rule apply only to traditional, combustible cigarettes); (2) the rule would contradict without explanation FDA's conclusions in the marketing order for Heatsticks; and (3) applying the rule would violate the First Amendment and raise potential concerns under the Takings Clause of the Fifth Amendment (thus, violating the APA). The comment states the proposed rule provides information and evidence only relating to traditional, combustible products and notes that none of the illness or conditions have been causally linked to Heatsticks used with the IQOS device. The comment also indicates that applying the required warnings would depart from FDA's

findings in the marketing order and FDA has failed to explain the apparent conflict between the order and the rule by failing to address FDA's previous conclusions regarding the health risks presented by Heatsticks used with the IQOS device.

The comment also states that applying the rule would violate the First Amendment because the required warnings must cover at least the top 50 percent of the front and rear panels of packages and 20 percent of advertisements, and the marketing order requires that 30 percent of the front and rear panels and 20 percent of each advertisement contain a nicotine warning, which would result in 80 percent of packages and 40 percent of advertisements being used for the "[G]overnment's anti-smoking message." This comment also notes this could raise issues under the Takings Clause of the Fifth Amendment.

Both comments also argue that, because the scope of the rule is cigarette smoking, and its goal is to promote greater public understanding of the negative health consequences of smoking, applying the required warnings to Heatsticks would be misleading as this product is a non-combustible product, which produces a nicotine-containing aerosol without combustion, and FDA has acknowledged these are materially different from combustible cigarettes. Given FDA's finding in the premarketing authorization orders that the products are appropriate for the public health, the comments suggest that FDA should tailor the warnings on Heatsticks to contain accurate and non-misleading information. The comments do not propose specific language for this purpose.

(Response 81) As these comments note, heated tobacco sticks are within the FCLAA's definition of cigarette (section 3(1) of the FCLAA), and, as such, are within the scope of the rule. Although IQOS Heatsticks may present different considerations from traditional cigarettes, FDA does not believe that a broad rule requiring cigarette health warnings generally is the appropriate

place to address the requirements as they apply to one specific product. Rather, FDA intends to make product-specific decisions about warnings, including decisions about potential product-specific changes to the cigarette health warnings required by this rule, when issuing or revising individual product marketing orders. There is no conflict or inconsistency between the warning regime required by the FCLAA (including its adjustments through this or potential future rulemakings under section 202 of the Tobacco Control Act) and requirements set by a marketing order, because FDA has authority to change the applicability of general warning requirements for a specific product via a marketing order. Among other relevant provisions, section 202(a) of the Tobacco Control Act (amending section 5(a) of the FCLAA) specifically states: "Except to the extent the Secretary requires *additional or different* statements on any cigarette package . . . by *an order, by an authorization to market a product, or by a condition of marketing a product, . . .* no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package" (emphasis added).

This approach allows FDA to review the evidence submitted in an application, including on the health risks of a specific product, and make any appropriate product-specific decisions about warnings based on that product-specific evidence. FDA already conducted such an evaluation in the context of the IQOS premarket tobacco product application (PMTA) marketing authorization order. FDA recognizes that the final rule amends the general warning regime for cigarettes and that FDA will need to consider the applicability of the new regime to the IQOS Heatsticks and revisit the terms of the PMTA order. As stated in the PMTA order, "[w]hen FDA promulgates a final rule with respect to health warnings for cigarettes, FDA will reevaluate the conditions of marketing with respect to warnings for the products subject to this order."

2. Section 1141. 3--Definitions

Proposed § 1141.3 included definitions for the following terms:

- Cigarette
- Commerce
- Distributor
- Front panel and rear panel
- Manufacturer
- Package or packaging
- Person
- Retailer
- United States

As discussed in the preceding paragraphs, we received some comments regarding the scope of this rulemaking and the definition of "cigarette," which we addressed in those paragraphs. We received no other comments related to these definitions, and we are finalizing this section without change.

3. Section 1141.5--Incorporation by Reference

Proposed § 1141.5 stated that certain material would be incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. Proposed § 1141.5 provided that all approved material would be available for inspection at the U.S. Food and Drug Administration, the National Archives and Records Administration, as well as available from the Center for Tobacco Products, FDA. Although we did not receive comment on the use of incorporated by reference materials, we did receive comments requesting clarifications on the substance of those materials. In the following paragraphs, we discuss the comments and our responses on this section. After considering the

comments, we made clarifications to this section and § 1141.10(b) and (d)(4) and (5) to more clearly state that the materials we are incorporating include the textual warning statement paired with its accompanying color graphic. It is this combination that must be accurately reproduced and meet the requirements of the FCLAA and part 1141. In addition, as described in section VII.B.5, FDA also has increased the contrast and size of the display in one image ("WARNING: Smoking during pregnancy stunts fetal growth") to improve image clarity. This change is reflected in the material that FDA is incorporating by reference.

The material incorporated by reference, entitled "Required Cigarette Health Warnings, 2020," includes the required warnings (comprising a textual warning statement, as specified in § 1141.10(a), and its accompanying color graphic) in different layouts based on the size and aspect ratio of the display area where the required warning must appear (i.e., on cigarette packages, in cigarette advertisements). We have included an electronic PDF file containing the required warnings as a reference in the docket for the final rule (Ref. 11). FDA is also making this material available on its website at <https://www.fda.gov/cigarette-warning-files>.

FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and sizes of cigarette packages and advertisements. To help prevent distortion of the image and text and to minimize the need for adaptation, FDA has created electronic, layered design files, built as .eps files, in different formats and aspect ratios designed to fit packaging and advertising of various shapes and sizes. FDA is not requiring the use of these .eps files, but rather we are providing the files as a resource to assist regulated entities implement part 1141. In addition to the materials incorporated by reference and the .eps files, FDA is making available a technical specifications document that includes information on how to access, select, use, and adapt the appropriate .eps

file based on the size and aspect ratio of the display area where the required warning must appear. These .eps files and technical specifications are also available on FDA's website at <https://www.fda.gov/cigarette-warning-files>.

(Comment 82) One comment requests that FDA release final electronic, layered design files for each required warning, as well as technical specifications before the final rule is released.

(Response 82) To assist regulated entities with implementation, we are providing the electronic, layered design files, as well as technical specifications, with the final rule. These materials are available at <https://www.fda.gov/cigarette-warning-files>.

4. Section 1141.10--Required Warnings

a. Section 1141.10(a) and (b)--required warnings.

In proposed § 1141.10(a) and (b), we proposed to establish required warnings, consisting of one textual warning statement with a specific color graphic to accompany the textual warning statement, which must be accurately reproduced from the materials incorporated by reference in § 1141.5 (proposed § 1141.10(a) and (b)). We received comments on the required warnings, and we discuss those comments and our responses in section VII. After reviewing public comments and weighing additional scientific, legal, and policy considerations, FDA is removing 2 of the 13 required warnings included in the proposed rule, and FDA is finalizing § 1141.10(a) and (b) with 11 required warnings. As described in the preceding paragraphs, FDA is also making clarifying changes to § 1141.10(b) to make it more apparent that it is the combination of a textual warning statement and its accompanying color graphic that we are incorporating by reference and that must be accurately reproduced in the appropriate size and format.

b. Section 1141.10(c)--packages.

We proposed that section 1141.10(c) establish a requirement for packages making it unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the FCLAA and this part. This section requires that: (1) The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping; (2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the front and rear panels of the carton and must comprise at least the left 50 percent of these panels; and (3) The required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation. We received comments on these requirements, including a comment that we add an additional requirement under § 1141.10(c). After review and consideration of the comments, FDA is finalizing this subsection without change.

(Comment 83) At least one comment suggests that the required warning on packages be at least 75 percent on the front and rear panels of the package, similar to the approach of other countries, such as Canada and Australia. Additionally, multiple other comments support the provision requiring the warning comprise at least the top 50 percent of the front and rear panels of cigarette packages, stating that this ensures that the required warnings are visible to consumers.

(Response 83) Section 4 of the FCLAA establishes size requirements, and FDA declines to increase the size of the required warnings. Based on the FCLAA, § 1141.10(c)(2) states that the required warnings must comprise at least the top 50 percent of the front and rear panels of the

package and that the required warnings must be located on the left side of the front and rear panels of cartons and comprise at least the left 50 percent of these panels.

(Comment 84) FDA received comments from both industry and public health organizations suggesting that the front and rear panels could carry separate warnings (i.e., a different warning on each side). One comment suggests this could provide more information to consumers, and other comments support this as a means of providing some flexibility to manufacturers, given printing and other considerations. Another comment suggests FDA could require warnings in different languages on the front and rear panels of the cigarette package or, through a future rulemaking, FDA could develop two separate images for each warning so that any given package would feature the same warning text on each side but a different depiction.

(Response 84) Section 4(a)(1) of the FCLAA is ambiguous as to whether it mandates the use of the same required warning on both the front and rear panels of the individual cigarette package, or allows two different required warnings to be used, one on the front panel and the other on the rear panel. At this time, we see no reason to mandate that the front and rear panels must carry the same required warnings. Accordingly, the current rulemaking permits manufacturers to use different required warnings if they wish. This is also consistent with Congress's intent that all of the required warnings be displayed in the marketplace at the same time (see section 4(c)(1) and (3) of the FCLAA). As the comments indicate, additional changes such as those suggested (e.g., requiring text in different languages, multiple images for each warning) could be considered in a further rulemaking.

(Comment 85) FDA received a comment suggesting that a subsection (4) be added to § 1141.10(c) to help ensure that the required warnings be unobstructed from view in the retail environment.

(Response 85) FDA declines to make this change as we anticipate that this concern will be adequately addressed by other provisions of the rule, such as § 1141.1(c) and § 1141.1(d). Under § 1141.1(c), a retailer would not be in violation of 1141.10 for packaging that: (1) contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or proposed part 1141. Under § 1141.1(d), the advertisement requirements apply to a retailer only if the retailer is responsible for or directs the warnings for advertising, but this provision does not relieve a retailer of liability if the retailer displays in a location an advertisement that does not contain a warning or that contains a warning that has been altered by the retailer in a way that is material to section 4 of the FCLAA or the requirements of part 1141. As discussed in the proposed rule, retailers would be in violation of the FCLAA and part 1141 if they alter cigarette packaging or advertising in a way that is material to these requirements. This could, for example, occur if a retailer obscures or covers the required warning (e.g., blocking with a sticker or marker), shrinks the warning, or uses a sleeve to cover the warning. Retailers also would be liable if they display, in a location open to the public, an advertisement that does not contain a warning.

c. Section 1141.10(d)--advertisements.

We proposed that § 1141.10(d) establish that it is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the FCLAA and part 1141. The proposed requirements provide, in part, that: (1) for print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile

applications, and email correspondence), the required warning must appear directly on the advertisement; and (2) the required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

In addition, we proposed in § 1141.10(d)(3) that the text in each required warning must be in the English language, except in the case of an advertisement that appears in a non-English medium, the text in the required warning must appear in the predominant language of the medium whether or not the advertisement is in English, and in the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning must appear in the same language as that principally used in the advertisement. We also proposed in § 1141.10(d)(4) and (5) that for English-language and Spanish-language warnings, each required warning must be obtained from the electronic files contained in "Required Cigarette Health Warnings," which would be incorporated by reference at § 1141.5, and be accurately reproduced as specified in "Required Cigarette Health Warnings," and for non-English-language warnings, other than Spanish-language warnings, each required warning must be obtained from the electronic files contained in "Required Cigarette Health Warnings," which would be incorporated by reference at § 1141.5, and be accurately reproduced as specified in "Required Cigarette Health Warnings," including the substitution and insertion of a true and accurate translation of the textual warning statement in place of the English language version. The inserted textual warning statement must comply with the requirements of section 4 of the FCLAA, including area and other formatting requirements, and this part.

In the following paragraphs, we discuss comments on these provisions. After carefully considering the comments, we are finalizing these provisions without substantive change;

however, as described earlier in this section, we made clarifications to § 1141.10(d)(4) and (5) to make it more apparent that it is the combination of a textual warning statement and its accompanying color graphic that we are incorporating by reference and that must be accurately reproduced in the appropriate size and format.

(Comment 86) Several comments note general support for the provision requiring that the required warning comprise at least 20 percent of the area of the advertisements stating that it is sufficient to ensure the required warnings are visible to consumers. FDA also received a comment requesting that we consider adding price promotions and coupons to the examples provided in § 1141.10(d) because many apps, mailers, and pop up ads contain only coupons or price promotions, like quick response codes.

(Response 86) FDA agrees with the general support for these provisions. We note that the list of examples included in this provision is not intended to be exhaustive, and that the requirements under part 1141 apply to all forms of cigarette advertising, regardless of the medium in which it appears. The final rule applies to advertisements appearing in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, internet web pages, electronic mail correspondence, or be communicated via mobile telephone, smartphone, microblog, social media website, or other communication tool; websites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution restriction in § 1140.34. We agree that the requirement that the required warning comprise at least 20 percent of the area of the advertisement in a conspicuous

and prominent format and location at the top of each advertisement within any trim area will help ensure the warnings are visible to consumers.

(Comment 87) Some comments address the translation of the textual warning statements into languages other than Spanish and express concerns that manufacturers or retailers might undermine the effectiveness of the required warning by using a language in the warning that is not appropriate to the audience reading or experiencing the advertisement. A comment suggests that if FDA does not provide warning translations in languages other than English and Spanish, then FDA should review any translated warning before the product can be advertised. Another comment recommends that FDA provide the translation of textual warning statements into languages most commonly used, other than English, to help ensure access to this information as a health equity measure.

(Response 87) Although we decline to provide additional translations, FDA does intend to monitor translations to ensure that they are accurately reproduced and will take action, as appropriate, to address any translations that do not meet the requirements of the FCLAA and the final rule. Under § 1141.10(d)(5) all non-English-language warnings, other than Spanish-language warnings, must be accurately reproduced as specified in "Required Cigarette Health Warnings, 2020," including the substitution and insertion of a true and accurate translation of the textual warning statement in place of the English language version. If a translation of a textual warning statement is not a true and accurate translation, as required by § 1141.10(d)(5), the cigarette will be deemed to be misbranded under section 903(a)(1) or 903(a)(7)(A) of the FD&C Act for failure to bear one of the required warnings in accordance with section 4 of the FCLAA and this part.

d. Section 1141.10(e) and (f)--other requirements.

In the proposed rule, § 1141.10(e) states that the required warnings must be indelibly printed on or permanently affixed to the package or advertisement. Proposed § 1141.10(f) establishes that no person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the FCLAA and this part, except as provided by § 1141.10(c) and (d). We received no comments regarding these specific proposed provisions and are finalizing § 1141.10(e) and (f) without change.

e. Section 1141.10(g)--cigarette plans.

Section § 1141.10(g)(1) proposed that the required warnings for packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, FDA. In addition, proposed § 1141.10(g)(2) provides that the required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributor, retailer to, and approved by, FDA. Under proposed § 1141.10(g)(3), FDA will review each plan submitted under this section and approve it if the plan: (1) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection and (2) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time. Under proposed § 1141.10(g)(4) each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA-approved plan under section 4 of the

FCLAA and this part must maintain a copy of such FDA-approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

After considering the comments on § 1141.10(g), we are finalizing this provision without change. We discuss both the comments and our responses in the following paragraphs.

(Comment 88) Some comments express general support both for the rotation requirements to reduce the risk of wear out and overexposure and for the submission of plans for approval by FDA. These comments encourage FDA to have in place robust compliance processes to assess whether manufactures, distributors, and retailers are meeting the requirements of this rule. Some comments note that "particular attention" be directed toward media and retailers serving people of color, people with low incomes, and LGBTQ populations.

(Response 88) We agree that the requirements related to cigarette plans are important to implementing the requirements of the FCLAA. The required warnings on packages must be randomly displayed and distributed in accordance with an FDA-approved plan. Similarly, the required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements, in accordance with an FDA-approved plan. Each tobacco product manufacturer must maintain a copy of the plan and make it available for inspection and copying by officers or employees duly designated by the Secretary. A cigarette will be deemed to be misbranded under section 903(a)(1) or 903(a)(7)(A) and (8) of the FD&C Act if its package or advertising does not bear one of the required warnings in accordance with section 4 of the FCLAA and this part. We further discuss the importance of enforcing these requirements in later paragraphs of this section (see section IX.B.6).

(Comment 89) Two comments raise concerns related to satisfying the "random and equal" requirement of proposed § 1141.10(g) for 13 different warnings without significant changes to packaging production. These comments note that because 13 is both a prime and odd number, printing 13 different warnings equally is incompatible with industry-wide printing practices. One comment suggests that FDA either require a random and equal distribution of 12 or 9 warnings or random but unequal display of 13 warnings. The other comment proposes that FDA require 9 different warnings and provide greater flexibility for the random and equal requirement because of printing method variation across the industry.

(Response 89) FDA is requiring 11 warnings, which we appreciate is also a prime and odd number and thus may present similar issues. We address some of these issues in section X. In addition, by permitting the front and rear panels to carry different warnings, the rule may mitigate some of these issues by giving manufacturers flexibility in how they meet the requirements of the rule. We also note that the FCLAA provides that the required warnings be "randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product," which we believe provides for some flexibility in the meaning of "equal," as defined below. Manufacturers with concerns about complying with this requirement should promptly reach out to FDA to discuss their approach for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding this requirement. We encourage manufacturers to submit their cigarette plan to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner. FDA intends to issue a final guidance document with additional information and recommendations

that may be helpful in preparing these plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

(Comment 90) Comments also raised concerns about satisfying the "random and equal" requirement within the 12-month period prescribed by proposed § 1141.10(g)(1), which states each required warning would be required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product. These comments asked for clarification of the phrase "as is possible" and asked for flexibility in achieving "equal distribution." At least two comments suggest a deviation allowance of 4 percent (or larger). These comments also note the difficulty of achieving equal distribution within the 12-month period specified and asked for a longer period in which to achieve equal distribution, suggesting that achieving the random and equal requirement within the 12-month period would be particularly challenging for products with low annual volume sales.

(Response 90) We recognize and understand the difficulties in achieving the random and equal display requirement within a 12-month period given the number of required warnings and agree that some level of deviation is appropriate particularly given the language of the FCLAA, which includes the phrase "as equal a number of times as is possible." The cigarette plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures to ensure random display, in as equal a number of times as is possible, in each 12-month period on each brand of the product. Manufacturers with concerns about complying with this requirement for their products should promptly reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding this requirement.

We encourage manufacturers to submit their cigarette plan to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner.

Additionally, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

(Comment 91) One comment requests that FDA accept in digital files (i.e., electronic art) the representative samples of packages and advertisements with each of the required warnings submitted with cigarette plans as FDA does for biannual tobacco product listing submissions. The comment notes that this would allow plans to be prepared quickly without the expense of engraving cylinders and obtaining proofs for each brand style. The comment also notes that the submission of physical packages would also be time-consuming, whereas the use of digital files would allow companies to more quickly respond without the time and expense of re-engraving cylinders.

(Response 91) FDA agrees that it is acceptable to voluntarily submit representative advertisements and packaging as digital files (i.e., electronic art) along with other information that the manufacturer elects to submit with the cigarette plan to ensure that it is complete. The information submitted should describe a plan to achieve the random and equal display and distribution of the required warnings on packages and the quarterly rotation of the required warnings in advertisements. As discussed in the section IX of the proposed rule, FDA is only requesting that the cigarette plan include representative samples of packages and advertisements with each of the required warnings. The samples are to place the cigarette plan in context and facilitate FDA's review of the plan. FDA's review of a cigarette plan is only for the purpose of determining compliance with the statutory and regulatory criteria for approval of a cigarette plan,

as set forth in section 4(c)(3) of the FCLAA and proposed § 1141.10(g)(3). Approval of a cigarette plan does not represent a determination by FDA that any specific package or advertisement complies with any of the other requirements under section 4 of the FCLAA and part 1141, or any other requirements under the FD&C Act and its implementing regulations. Additionally, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

(Comment 92) FDA also received at least one comment requesting FDA clarify in the final rule that retailers are not required to submit plans for random and equal display of the required warnings for packages and quarterly rotation of the required warnings in advertisements. The comment notes that requiring retailers to submit a plan exceeds FDA's authority, would unduly burden retailers, and is not achievable as retailers have no control over which health warning is displayed as they receive the cigarette packages that they sell, and often the advertisements they use, from tobacco product manufacturers and distributors.

(Response 92) With respect to the concerns related to retailers, § 1141.1(c) and (d) explain when a retailer is not in violation of the FCLAA and § 1141.10. Under § 1141.1(c), retailers typically would not be required to submit a cigarette plan for packaging, as long as the cigarette packaging: (1) contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or part 1141 (see § 1141.1(c)). We believe most, if not all, retailers would fall under this scenario. Retailers who are also manufacturers will be subject to both the requirements for retailers and manufacturers, as applicable. Retailers that are responsible for or direct the warnings for advertising will be required to submit a cigarette plan

for advertising and would be subject to the advertisement requirements set forth in § 1141.10(d). We note, however, this provision will not relieve a retailer of liability if the retailer displays in a location open to the public an advertisement that does not contain a warning or that contains a warning that has been altered by the retailer in a way that is material to section 4 of the FCLAA or the requirements of this proposed part.

We discuss these provisions in more detail in the section IX of the proposed rule. In general, based on FDA's experience reviewing plans for other tobacco products, we believe it is likely that for domestic products only one cigarette plan will be submitted for each brand and that the brand's manufacturer will submit this plan because, in most instances, the brand's manufacturer is the entity best able to ensure that a plan meets the relevant requirements. The brand's manufacturer is also typically the entity responsible, either directly or through a contractor or other agent, for placing or directing the placement of the required warnings on the brand's cigarette packages and for directing distribution. For cigarettes that are imported, the importer (included in the definition of manufacturer) usually directs distribution of the packages after they are imported. Therefore, for imported cigarettes, the importer is likely best-positioned to submit the plan. To further aid in the understanding of the cigarette plan requirements, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

5. Section 1141.12--Misbranding of Cigarettes

Under proposed § 1141.12 a cigarette would be deemed to be misbranded under section 903(a)(1) of the FD&C Act if its package does not bear one of the required warnings and will be deemed to be misbranded under section 903(a)(7)(A) of the FD&C Act if its advertising does not

bear one of the required warnings in accordance with section 4 of the FCLAA and this part. In addition, under proposed § 1141.12(b) a cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor would be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the FD&C Act if it bears one of the required warnings in accordance with section 4 of the FCLAA and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the FD&C Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the FCLAA and this part. We received no comment regarding proposed § 1141.12, and we are finalizing this section without change.

6. Other comments--Compliance

(Comment 93) FDA received some general comments related to enforcement of the rule. These comments encourage FDA to ensure enforcement of the required warnings on packages and advertisements particularly in neighborhoods of low SES. The comments suggest that surveillance and fines may improve compliance. Other comments recommend that FDA be mindful of vendors who, although illegal, might sell merchandise such as from their backpacks.

(Response 93) FDA agrees that enforcing warning requirements is important. FDA conducts routine monitoring and surveillance of the manufacturing, marketing, sales, distribution, labeling, advertising and other promotional activities of regulated tobacco products for compliance with applicable provisions of the FD&C Act. FDA has a range of tools to help ensure compliance with tobacco product regulations. Failure to comply with the FCLAA, FD&C Act, or their implementing regulations may result in FDA initiating action, including, but not

limited to, warning letters, civil money penalties, no-tobacco-sale orders, seizures, injunction, or criminal prosecution. Additionally, misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

(Comment 94) Another comment also suggests that FDA require manufacturers to submit inventory information, including information on levels of inventory and when it is expected to be sold, as a means of distinguishing cigarette packages sold from existing inventory from inventory manufactured after the effective date. The comment recommends FDA ask for information on how to read date codes to help the Agency better understand which manufacturers may not be complying with the rule.

(Response 94) FDA declines to adopt these suggestions as section 201(b) of the Tobacco Control Act imposes a requirement that, beginning 30 days after the effective date of the final rule, manufacturers would not be permitted to introduce into domestic commerce any cigarette packages that do not contain the required warnings, irrespective of the date of manufacture. FDA believes this requirement addresses the concern related to ensuring compliance with the required warnings.

X. Comments Regarding Implementation Issues

Some comments raise questions related to implementing the requirements of the final rule. We describe and address those comments in the following paragraphs.

(Comment 95) FDA received comments objecting to the proposed rule as based on a fundamental misunderstanding of the processes used to print the vast majority of cigarette packaging in the United States, which one comment states is a gravure process using engraved cylinders. These comments state the rule would place significant and unnecessary burdens on industry because the requirement of random and equal display and distribution is infeasible.

(Response 95) We disagree that the rule is based on a fundamental misunderstanding of the processes used to print the vast majority of cigarette packaging in the United States. We respond to this particular concern in more detail in the Final Regulatory Impact Analysis that is issuing with the final rule (Ref. 16), but we note generally that (contrary to the comment's suggestion) FDA's Labeling Cost Model does assume that 95 percent of cigarette UPCs will be printed using the gravure method.

In addition, we recognize and understand that achieving conformity with the narrowest possible reading of the random and equal display requirement within a 12-month period would pose some difficulties, and we agree that allowing some level of deviation is appropriate particularly given the language of the FCLAA, which includes the phrase "as equal a number of times as is possible." As we discuss in section IX, the cigarette plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures to ensure random display, in as equal a number of times as is possible, in each 12-month period on each brand of the product. Manufacturers with concerns about complying with this requirement for their products should promptly reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding this requirement. We encourage manufacturers to submit their cigarette plan to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner. Additionally, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

(Comment 96) One comment requests "Printer's Proofs" for each required warning to facilitate consistent reproduction of the color images. The comment notes that manufacturers use different ink application techniques and substrates, which could result in altered appearances of the warnings on packs.

(Response 96) FDA intends to provide Printer's Proofs upon request. Regulated entities can request a set of SWOP or GRACoL Printer's Proofs for the required warnings (each set will contain a total of 22 proofs: the 11 required warnings with black text on white backgrounds and the 11 required warnings with white text on black backgrounds). Requests can be submitted by email (cigarettewarningfiles@fda.hhs.gov), phone (1-877-CTP-1373) or regular mail (Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, ATTN: Office of Health Communication and Education, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002).

(Comment 97) One comment discusses a challenge with accurately reproducing the required warnings on a variety of cigarette package shapes and sizes. The company asked that FDA provide specific direction for permissible adjustments to the required warnings and that FDA tolerate minor variances in how the warnings appear on cigarette packaging.

(Response 97) As discussed in section IX.B.3, we are providing the required warnings in a variety of sizes and formats as incorporated by reference materials. In addition, we are providing electronic, layered design files in an .eps format, which manufacturers may use in developing their packaging and labeling, as well as technical specifications to selecting, using, and adapting these files. These documents will provide extensive information and help manufacturers accurately reproduce the required warnings for different packages shapes and sizes.

(Comment 98) One comment requests that FDA clarify how manufacturers should incorporate the required warnings on packs with hinged lids. The comment states that the content of warnings printed on the hinged lids can shift up or down by about 1 mm at the point where the lid meets the front of the pack due to normal variations in production of the packaging. These comments recommend that FDA design the warnings with all text located either above or below the hinged lid, allow for minor variations in how the required warnings appear on cigarette packs due to this manufacturing variability, or provide font suitcases and instructions for use that allow manufacturers to flow text freely within a designated text area to ensure that the text is not interrupted.

(Response 98) To ensure that the warning is clear and legible on hinged lid packages, FDA is allowing for minor variations in how the required warnings appear. Manufacturers can separate two lines of text within the textual warning statement such that the line at the location where the lid is to open cuts across the background space between two lines rather than through a line of text. This will help ensure that the textual warning statement is not severed when the package is opened and is clear, conspicuous, and legible in accordance with section 4 of the FCLAA. We note that product packages with hinged lids are widely prevalent in countries that already require pictorial cigarette warnings and, based on that experience, we conclude that this new provision should provide companies with flexibility for displaying the warnings on packages with hinged lids.

(Comment 99) One comment requests that FDA allow manufacturers to position warnings below soft pack closures. The comment explains that the top of a cigarette soft pack is folded down and held down by an adhesive closure that is applied after the packages have been printed. Without any accommodation, that closure would obstruct a portion of the required

warnings. The comment notes that in FDA's 2011 rulemaking, the Agency permitted manufacturers to "adapt the warnings on 'soft pack' style packaging by moving the warning below the closure" (76 FR at 36691), but the comment asserts that the 0.375 inch boundary that FDA previously contemplated is too small to ensure there is enough adhesive for the package to remain closed while accounting for standard printing variations. Instead, the comment requests that FDA should allow the closure to extend up to 0.482 inches from the top of the edge of the package.

(Response 99) FDA disagrees. As in 2011, we recognize the technological difficulty of incorporating the required warnings on "soft pack" style packaging. Given the paramount need to incorporate the warning without obstructing any of the elements of the warning (i.e., the image and the textual warning statement), a company may adapt the warnings on "soft pack" style packaging by moving the warning below the closure. Because of the importance of maintaining the integrity of the required warning (e.g., not distorting the image or text), an adaptation of 0.375 inches may be acceptable only when it is not technologically feasible to incorporate the required warnings on "soft pack" style packaging without the need to adapt the required warning and the required warning after the adaptation is still accurately reproduced (e.g., the required warning is not distorted). Anything in excess of 0.375 inches may begin to distort the required warning and likely would not be in compliance with the requirements of the FCLAA and part 1141. We strongly encourage manufacturers to reach out to us to discuss these issues.

Under this approach, companies using "soft pack" style packaging could move only the upper boundary of the display area of the warning so that it runs along a line that is parallel to and not more than 0.375 inches from the top edge of the package. The companies may compress the vertical size of the image and then shift it down (so that it stays within the top 50 percent of

the package), but companies who do this must ensure that, to the extent the required warning must be adapted to fit the dimensions of the warning area below the closure, the proportions of the required warning must be maintained. In addition, the closure and the portion of the packaging that appears between the top edge of the package and the upper boundary of the display area of the required warning must be either solid black or solid white. This will allow companies to continue to produce "soft pack" style packaging with closures at the top center of the pack without obstructing the required warning. However, if we determine that it would be technologically feasible to incorporate the required warnings on "soft pack" style packaging without the need to adapt the warning in this way, we plan to notify the regulated companies and the public of this conclusion and give regulated companies a reasonable amount of time to modify their packaging before any regulatory action is taken under this rule.

(Comment 100) Some comments request clarifications on implementing the advertising requirements when the advertisement is what they call "small" or digital. For example, one comment notes that the proposed rule does not provide clarification regarding the display of warnings in digital advertisements. The comment asks that FDA evaluate existing digital platforms and provide specific direction on how to display the required warnings based on specific devices and software prior to finalizing the final rule. Another comment notes challenges related to displaying the warnings on small advertisements in a way that is not illegible or distorted. This comment suggests that FDA exempt small advertisements from the warning requirements or revise the minimum font requirements and use an appropriate image specifically designed for small formats.

(Response 100) Although FDA acknowledges that implementing the requirements for certain small advertisements and some digital advertisements may present specific challenges in

certain cases, we decline to exempt small advertisements. In both the case of digital advertisements or small advertisements, FDA invites manufacturers to raise the specific implementation issue they have as part of the submission of the plan under § 1141.10(g) to facilitate a solution that reflects the requirements and is also technically feasible for the manufacturer or other responsible entity.

XI. Effective Dates

In the proposed rule, FDA proposed that the required warnings for packages and advertisement become effective 15 months after the date the final rule publishes in the *Federal Register*, consistent with the language of section 201(b) of the Tobacco Control Act. FDA also proposed an effective date for the submission of plans under § 1141.10(g) of no later than 5 months after the final rule publishes in the *Federal Register*. Section 201(b) of the Tobacco Control Act provides that, beginning 30 days after the effective date, a manufacturer must not introduce into domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the FCLAA, as amended by the Tobacco Control Act. As provided by section 201(b) of the Tobacco Control Act, after the 30-day period, manufacturers would not be permitted to introduce into domestic commerce any cigarette packages that do not contain the required warnings, irrespective of the date of manufacture. In the proposed rule, we also requested comments regarding ways to differentiate cigarette packages sold from existing inventory from those that were manufactured after the effective date.

We received comments on both of these proposed effective dates, as well as the 30-day period. Following consideration of the comments as described below, the final rule continues to include an effective date of 15 months from the date the final rule publishes in the Federal

Register, as required by section 201(b) of the Tobacco Control Act. However, after further consideration, we are no longer including a 5-month effective date for the submission of cigarette plans to FDA. The FCLAA and § 1141.10(g) require manufacturers to submit plans for the display and distribution of required warnings on cigarettes packages and the rotation of required warnings on cigarette advertising and to obtain FDA approval of their plans before products required to bear such warnings enter the market. Therefore, we strongly encourage entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within 5 months after the publication of this final rule. In addition, as directed by section 201(b) of the Tobacco Control Act, after the 30-day period, manufacturers will not be permitted to introduce into domestic commerce any cigarette packages that do not contain the required warnings, irrespective of the date of manufacture.

(Comment 101) Some comments identify a challenge with complying with the implementation deadline of 15 months after publication of the final rule. These comments note that once the final rule is published it will take time to redesign packaging to include the new required warnings, submit plans to FDA for review, work with printers to develop printing processes to print the new required warnings in accord with their approved plans, and then print new packs. These comments request an extension of the 15-month deadline, that FDA toll (i.e., pause) the deadline during the Agency's review of the rotational plans, or both, or that FDA use enforcement discretion to allow companies greater than 15 months to come into compliance. A comment suggests FDA is obligated to determine the length of time it will take manufacturers to engrave cylinders and print labels and provide a sufficient amount of time to comply with the rule. This comment notes that the number of cylinders that need to be engraved will depend on the number of required warnings, which could result in thousands of cylinders, that there are two

main printing companies used by the industry, that manufacturers may need additional time to redesign their labels to use fewer colors, and lastly, that manufacturers cannot get a head start because of uncertainty around the rule surviving constitutional challenge or being subject to severability. One comment requests that FDA clarify that "distributors and retailers can continue to distribute and sell for an unlimited sell-through period products manufactured before the effective date and introduced into commerce by the manufacturer within 30 days of the effective date." This comment asserts that small tobacco product manufacturers cannot afford the hardship of product returns by distributors and retailers who may be uncertain of their ability to sell products that do not bear the required warnings.

Other comments encourage the Agency to maintain the proposed rule's timelines for implementation (e.g., submitting cigarette plans no later than 5 months after publication of the final rule and implementing the warnings no later than 15 months after publication of the final rule) as they are reasonable and consistent with the FCLAA, especially given the time that has elapsed since the issuance of the initial rule in 2011 and that the public has been deprived of the benefits of the required warnings for almost a decade due to FDA's slow response in proposing this rule. These comments note that industry has been on notice of the required warnings since the enactment of the Tobacco Control Act and manufacturers have implemented pictorial cigarette warnings in more than 100 other countries.

(Response 101) We agree with the comments that suggest we maintain the proposed 15-month deadline for the effective date of the required warnings, consistent with the Tobacco Control Act. Consistent with the statute, we believe it is also important to maintain the 30-day period after which products may not be introduced into domestic commerce by the manufacturer, and we disagree that further clarification of this is necessary. Although we acknowledge that

there may be some challenges as industry moves to implement these requirements, FDA intends to assist manufacturers, distributors, and retailers, as applicable, with specific questions and concerns regarding these requirements. Manufacturers with concerns about complying with this requirement for their products should reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding compliance with the warning requirements.

Section 201(a) of the Tobacco Control Act requires manufacturers to submit plans for the display and distribution of required warnings on cigarettes packages and the rotation of required warnings on cigarette advertising, and to obtain FDA approval of their plans before products required to bear such warnings enter the market. Therefore, for products that will be on the market as of the effective date of the required warnings, manufacturers must submit, and FDA must approve, their plans ahead of the required warnings' effective date. FDA strongly encourages entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within five months after publication of this final rule. Doing so will benefit regulated industry, based on the comments the Agency received regarding the time firms may need to work with printers to implement the required warnings as outlined in their approved plans. Early submission will facilitate timely FDA review prior to the effective date of the required warnings, encourage dialogue with entities regarding any implementation concerns, and provide time to consider proposals by entities in a timely manner. Given the initial high volume of original submissions FDA may receive and based on our experience with review of plans for required warnings on other tobacco products, our best estimate is that it will take up to 6 months for the Agency to review those original submissions. FDA will ensure that its review of cigarette

plans will be completed no later than 6 months after receipt of an adequate plan from persons who work in good faith with FDA to complete its review (e.g., persons should work diligently with FDA and be responsive by submitting any requested information in a timely manner). If there is a higher volume of submissions received than currently expected, for those entities who submit an adequate plan within 5 months of publication of this final rule and who work in good faith with FDA to complete its review, FDA intends to ensure that entities are not delayed or prevented from distributing cigarette packages or advertising their products due to the Agency's not having approved their plans by the effective date of the final rule. In addition, FDA intends to issue a final guidance document that is intended to assist entities with developing their cigarette plans, which, when issued, may be found at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

XII. Severability

Consistent with section 5 of the Tobacco Control Act, FDA intends for the various requirements established by this rulemaking to be severable. Section 5 of the Tobacco Control Act states that, if any provision of a regulation issued under the Tobacco Control Act is held to be invalid, the remainder of the regulation "shall not be affected and shall continue to be enforced to the fullest extent possible." (Section 5 of the Tobacco Control Act is codified at 21 U.S.C. 387 note.) FDA has concluded that the individual aspects of this rule are workable on their own and should go forward in the event that some are invalidated. As discussed below, FDA has determined that severability both is consistent with Congressional intent and would best advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

The rule is sound in its entirety and should be upheld in full. However, in a circumstance where some but not all of the rule's provisions are invalidated, FDA's intent is for the other provisions to go into effect. A key question to determining severability is whether the remaining portions of a regulation "could function sensibly without the stricken provision." *MD/DC/DE Broadcasters Ass'n v. F.C.C.*, 236 F.3d 13, 22 (D.C. Cir. 2001). Here, FDA has considered each provision independently and concluded that the individual portions of this rule are workable on their own.

In the event that some portions of the rule are stricken, FDA has concluded that each other portion of the rule would "function sensibly" on its own and should go into effect. As the proposed rule indicated, if a court were to invalidate some of the cigarette health warnings (i.e., text-and-image pairings), but some of the pairings remained valid, FDA intends that the remaining required warnings would go into effect. As another example, if a court were to invalidate some but not all of the images within the cigarette health warnings, FDA intends that those images would be severed and the corresponding textual warning statements would go into effect without the invalidated images, along with the remaining cigarette health warnings that pair a textual warning statement with an image. As a third example, if a court were to invalidate all of the images within the cigarette health warnings, FDA intends for the invalidated images to be severed and all the warnings to go into effect with only their textual warning statements.

Among other things, FDA has considered the statute's rotation and distribution requirements in reaching its conclusion that all portions of the rule can function sensibly and should take effect if any portions are invalidated. In the event that any warnings specified in this final rule do not go into effect, the requirements for warnings to be randomly and equally displayed and distributed on packages and quarterly rotated in advertisements will be applied to

the remaining warnings, such as remaining text-and-image pairings or textual warning statements without images.

FDA's intent for any invalidated portions of the rule to be severed also advances Congress's intent to replace the stale 1984 Surgeon General's warnings and to promote greater public understanding of the negative health consequences of cigarette smoking, since the remaining warnings could go into effect much earlier than could any different warnings implemented by other, subsequent means, such as further Agency rulemaking.

Several comments made remarks supporting or opposing the severability of the rule's provisions.

(Comment 102) One comment objects to any severing of the rulemaking because it asserts that FDA did not justify each permutation presented in the proposed rule, and severing the rulemaking would deny interested parties sufficient notice to participate in a meaningful notice and comment process. The comment suggests that section 5 of the Tobacco Control Act does not mandate severing the rulemaking in this situation. In addition, one comment states that because the Tobacco Control Act mandates that the textual warning statements must be accompanied by color graphics, FDA does not have the discretion to implement the textual warning statements only. This comment asserts that FDA is not authorized to change the placement of the warnings or reduce the statutory 50 percent size requirement. Another comment stated that implementation of only portions of the regulation would not be workable from a practical standpoint of rotating, distributing, and displaying the required warnings on cigarette packages and advertisements.

In contrast, other comments support severability, arguing that should any portion of the rule be invalidated, considering other parts severable and workable is consistent with section 5 of

the Tobacco Control Act and Congressional intent. Some comments specifically recommend that should a court invalidate any portion or block the images, the remaining portions should go into effect, as they would promote greater public understanding of the negative health consequences of cigarette smoking. Some comments suggest that severability is appropriate, but FDA should further explain its rationale to ensure judicial consideration of severability, if necessary, to prevent vacation of the entire rule should a court find any portion objectionable. One comment addresses the various scenarios FDA set out in the proposed rule with suggestions of how FDA should proceed in each case. That comment suggests that, if a court blocks the images, FDA should proceed with implementing the textual warning statements and, even if the size of the warnings is reduced, FDA should prioritize maintaining the warning at the top of the pack because of the importance of visibility of the warning.

(Response 102) FDA agrees with comments asserting that, if a portion of this rule is invalidated, severability would be appropriate. Case law supports that conclusion, including case law regarding the severability of statutory provisions. The Supreme Court in *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678 (1987), set forth the test for severability of statutory provisions, emphasizing that "a court should refrain from invalidating more of the statute than is necessary." *Id.* at 684 (brackets omitted). There are two prongs to the examination. First, a court should evaluate whether "the Legislature would [] have enacted those provisions which are within its power, independently of that which is not," i.e., "whether the statute will function in a *manner* consistent with the intent of Congress" if it is stripped of its unconstitutional provisions. *Id.* at 684, 685. Then, the reviewing court will consider whether "what is left is fully operative as a law," or if instead "the balance of the legislation is incapable of functioning independently." *Id.* at 684 (quotation marks omitted).

The same test is used to determine whether the invalid portion of a statute or the invalid portion of a regulation may be severed from the rest. *See United States v. Smith*, 945 F.3d 729, 738 (2d Cir. 2019) (citing decisions addressing statutory severability for the standard to determine regulatory severability). "Whether the offending portion of a regulation is severable depends upon the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broadcasters Ass'n v. F.C.C.*, 236 F.3d 13, 22 (D.C. Cir. 2001). *See also K-Mart Corp. v. Cartier*, 486 U.S. 281, 294 (1988) (severing a portion of a Customs Service regulation as being in conflict with the statute).

As noted, FDA intends for every portion of this rule to be severable and has concluded that, if some but not all portions of the rule were invalidated, remaining portions could and should function sensibly on their own. FDA's conclusion is informed by Congress's express intent. FDA agrees with the comments that section 5 of the Tobacco Control Act, entitled "Severability," expressly signals Congress's intent for regulations issued under the statute to be severable and for any remaining portion to be legally enforceable should any portion be found invalid. Section 5 provides in relevant part that "[i]f any . . . of the regulations promulgated under this division . . . is held to be invalid, the remainder . . . shall not be affected and shall continue to be enforced to the fullest extent possible." The inclusion of section 5 in the Tobacco Control Act creates a presumption that Congress intended for any invalid portion of a regulation issued under the statute to be severable from the remainder. *Alaska Airlines*, 480 U.S. at 686 (same, for statutes; holding that when Congress explicitly provides for severance by including a severability clause in a statute, there is "a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision"). Here, taking into consideration this statutory provision and Congress's stated goals in requiring these

warnings, FDA is explicitly stating its intent that the portions of this regulation be interpreted as severable. Therefore, the courts can say without any doubt, and all the more strongly "without any substantial doubt[,] that the agency would have adopted the severed portion on its own." *Am. Petroleum Inst. v. Env'tl. Prot. Agency*, 862 F.3d 50, 71 (D.C. Cir. 2017) (quotation marks omitted), *modified on other grounds*, 883 F.3d 918 (D.C. Cir. 2018).

The second prong of a severability analysis is whether the remaining portions of a statute or regulation remain workable on their own. In this case, they do. The different text-and-image pairings and the different textual warning statements can be and are intended to be incorporated into the label of a package or an advertisement on an individual basis and therefore "operate entirely independently of one another." *Davis Cty. Solid Waste Mgmt. v. U.S. E.P.A.*, 108 F.3d 1454, 1459 (D.C. Cir. 1997) (internal citation omitted). Because the Agency intends as many of the warnings to go forward as possible, and because the regulation will function even if some of the text-and-image pairings or the images are invalidated, any provisions of this rule that may be invalidated are properly severable.

With respect to the comment asserting that FDA lacks the discretion to implement the warning requirements with textual warning statements only or with other deviations from the statutory mandate, FDA notes that the question of severability is distinct from that of the Congressional directive to issue a warning regulation in the first instance. The situation that is the subject of this "Severability" section--i.e., the circumstance where a court has disagreed with FDA's conclusions as to the legality of some but not all provisions of the rule--raises different questions from those addressed in the comment. Contrary to what the comment states, FDA is not asserting, and does not need to assert, that it has the authority to promulgate a rule under section 15 U.S.C. 1333 that deviates from the requirements of section 1333. Instead, FDA here is

asserting, and need only assert, that in the event that a court invalidates certain provisions of this rule but not others, FDA intends the remaining provisions to go into effect on their own.

To the extent that the comment questions FDA's authority to oversee implementation of text-only warnings in the event of a court decision invalidating the images but upholding the rest of the rule, FDA disagrees. The comment asserts that, because the Tobacco Control Act directs FDA to issue color graphics to accompany the textual warning statements, FDA is without authority to implement the remaining portions of a rule if a court invalidates the color graphics but not the textual statements. FDA disagrees with any interpretation of the statute that would compel this result. Again, the question here relates only to severability and to what details of the regulation are preserved in the case where some provisions do not survive. The statute provides that FDA "shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)" (section 201(a) of the Tobacco Control Act). But this language does not dictate that, if some of the text-and-image pairings, images, or textual warning statements were invalidated by a court while other pairings, images, or statements were not invalidated, the result would be to invalidate all of the rule's requirements. For the reasons described above, in the event that some provisions of this rule are invalidated, the statute compels, FDA intends, and courts should recognize as workable the preservation of all remaining portions.

FDA disagrees with comments that suggest that stating its intentions for severability fails to provide the public with adequate notice of the portions of the rule that would take effect if any others are severed and prevents meaningful public comment. The public has had the opportunity to comment on the entire proposal, as well as each required textual warning statement and each

required text-and-image pairing, and thus all portions that may take effect if other portions are severed.

FDA also disagrees with comments suggesting that, if, for example, a court struck down any or all of the images but upheld the textual warning statements, the remaining unsevered portions of the rule would not be consistent with the intent of Congress. While it is clear that in section 201 of the Tobacco Control Act Congress intended for color graphics to accompany textual warning statements, and while the affirmative proposal of a regulation by FDA under section 201 requiring only textual warnings would not effectuate that specific intent, this analysis does not answer the question of severability, i.e., of what provisions of a regulation should survive in the event that a court strikes down some but not all provisions of this rulemaking replacing the Surgeon General's warnings with new text-and-image pairings. Here, Congress's intent surely supports preservation. It was clearly the intent of Congress by passing the Tobacco Control Act to replace the stale 1984 Surgeon General's warnings and to increase the size and update the placement of new required cigarette warnings, as well as to require color graphics. In the event that a court determines that a rule is valid with respect to the new textual warning statements but is not valid with respect to other aspects, including the color graphics, implementation of those other aspects would be consistent with Congress's intent to strengthen cigarette warnings.

Likewise, FDA disagrees with comments that it would be unworkable for warnings containing only textual warning statements or only text-and-image pairings that were not invalidated to take effect. FDA is aware of no technical, practical, or other impediment to implementation of individual provisions of this rule without the others. Thus, in the context of the question of severability, FDA concludes that the implementation of warnings containing only

textual warning statements would be workable (i.e., if all of the images are struck down), as would the implementation of a smaller number of required warnings (i.e., if some of the text-and-image pairings were found to be invalid and were severed, leaving fewer total pairings or a mixture of warnings that included both text-only and text-and-image pairings). FDA notes that comments do not provide details about why or how the implementation of portions of the regulation would not be workable. However, if companies have specific questions, FDA is ready to work with them regarding implementation issues.

XIII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order (EO) 12866, EO 13563, EO 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). EOs 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). EO 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is an economically significant regulatory action as defined by EO 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We estimate that for a small manufacturer or importer who would be affected by this final rule, initial costs could represent between 2.3 and 42 percent of their annual receipts and recurring costs could represent from 0.1

to 2.7 percent of their annual receipts. Hence, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in any year that meets or exceeds this amount.

This final rule requires that one of 11 new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, in the form of a photorealistic image, appear on cigarette packages and in cigarette advertisements. The final rule further requires that, for cigarette packages, the required warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed throughout the United States in accordance with a plan approved by FDA. The final rule also requires that, for cigarette advertisements, the required warnings must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA.

Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning about the negative health consequences of smoking, and benefit diverse populations that have disparities in knowledge about the negative health

consequences of smoking. We do not predict the size of these benefits at this time. We discuss the informational effects qualitatively.

The costs of this final rule consist of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. Using a 20-year time horizon, we estimate that the present value of the costs of this final rule ranges from \$1.5 billion to \$1.7 billion, with a mean estimate of \$1.6 billion, using a three percent discount rate, and ranges from \$1.1 billion to \$1.3 billion, with a mean estimate of \$1.2 billion, using a seven percent discount rate (2018\$). Annualized costs, which are presented below in Table 1, range from \$100 million per year to \$114 million per year, with a mean estimate of \$107 million per year, using a three percent discount rate, and range from \$107 million per year to \$122 million per year, with a mean estimate of \$114 million per year, using a seven percent discount rate (2018\$).

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a break-even approach. If the information provided by the cigarette health warning on each cigarette package were valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.

Table 1.--Summary of the Informational Effects and Costs of the Final Rule (in millions of 2018\$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Informational Effects		Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking, and help reduce disparities in knowledge about the						

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
		negative health consequences of smoking across diverse populations. If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.						
Costs	Annualized Monetized \$millions/year	\$114.4	\$106.6	\$122.2	2018	7%	20 Years	Effective date of 15 months from date of publication of final rule.
		\$106.7	\$100.0	\$113.5	2018	3%	20 Years	

In line with EO 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. With a seven percent discount rate, discounted relative to year 2016, the estimated annualized net costs equal \$73 million in 2016 dollars over an infinite horizon. Based on these costs, this final rule is considered a regulatory action under EO 13771.

Table 2.--EO 13771 Summary Table (in millions of 2016\$, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)
Present Value of Costs	\$1,046.0
Present Value of Cost Savings	\$0.0
Present Value of Net Costs	\$1,046.0
Annualized Costs	\$73.2
Annualized Cost Savings	\$0.0
Annualized Net Costs	\$73.2

Note: Effective date is 15 months from date of publication of final rule.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 16) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

XIV. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Additionally, the action is not anticipated to pose serious harm to the environment and to adversely affect a

species or the critical habitat of a species as stipulated under 21 CFR 25.21(b). Therefore, neither an environmental assessment nor an environmental impact statement is required.

XV. Paperwork Reduction Act of 1995

The final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) (PRA). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Required Warnings for Cigarette Packages and Advertisements

Description: The requirement for submission of plans for cigarette packages and advertisements, and the specific marketing requirements relating to the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in alternating sequence in cigarette product advertising, appear in § 1141.10(g). A record of the FDA-approved plan must also be established and maintained.

Description of Respondents: The respondents to this collection of information are manufacturers, distributors, and certain retailers of cigarettes who will be required to submit plans for cigarette packages and advertisements to FDA.

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the *Federal Register* of August 16, 2019 (84 FR 42754). No PRA-related comments were received.

FDA requests that each cigarette plan cover both packaging and advertising as applicable. The tobacco product manufacturer, distributor, or retailer should demonstrate how they plan to achieve the random display in each 12-month period, in as equal a number of times as is possible on each brand of the product, and random distribution in all areas of the United States of the required warnings on packages and the quarterly rotation in advertisements. Required warnings for cigarettes must be randomly displayed, in as equal a number of times as is possible, and randomly distributed on packages, and rotated quarterly in advertisements, in accordance with an FDA-approved plan.

FDA strongly encourages entities to submit their cigarette plans as soon as possible after publication of this final rule, and in any event within 5 months after publication of this final rule. Packages and advertisements of cigarettes are required to bear the required warnings beginning 15 months after the date of publication of the final rule. FDA intends to request an amendment to a plan under review if FDA needs clarification of information in the plan or other additional information to determine whether it could approve the plan. Any such amendments would likely increase the overall review time.

After FDA approval of an initial plan, a supplement to the approved plan should be submitted to FDA and approved before making changes to the random and equal display or distribution of required warnings on packages or the quarterly rotation of required warnings in advertisements. For a new brand, a new plan or a supplement to an FDA-approved plan is required to be submitted and approved before distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an FDA-approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under

section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warnings for all brands.

FDA allows electronic submissions, via FDA's Electronic Submissions Gateway, and written submissions. FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing.

For each brand of cigarettes, the plan for packaging should explain how: each of the required warnings will be randomly displayed during each 12-month period on each brand; each of the required warnings will be displayed in as equal a number of times as possible on each brand of the product; and product packages will be randomly and equally distributed in all areas of the United States in which the product is marketed. FDA expects that a plan for random and equal display and distribution of required warnings on packages will ordinarily be based on the date of manufacture or shipment of the product. For each cigarette brand, the plan for advertising should explain how the required warnings will be rotated quarterly in advertisements and how the quarterly rotations will occur in alternating sequence. Among other things, the plan should specify the initial rotation timeframe on which quarterly rotation is based and, if the rotation timeframe varies for different types/forms of advertising, specify the different quarterly timeframes associated with the different types/forms of advertising, and describe the quarterly schedule for rotating each of the required warnings for each cigarette brand. FDA would not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable FDA to approve the plan.

FDA's review of a plan would only be for determining compliance with the regulatory criteria for approval of a plan, as set forth in §1141.10(g)(1) and (2). FDA requests that plans submitted for review include representative samples of packages and advertisements with each of the required warnings. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan, not a review of the content of the package labels and advertisements. Approval of a plan does not represent a determination by FDA that any package or advertisement complies with any of the other requirements regarding the placement, font type, size, and color of the warnings found in section 4 of the FCLAA and part 1141, or any other requirements under the FD&C Act and its implementing regulations.

FDA intends to communicate the approval of a plan with a letter to the submitter. After FDA approval of an initial plan, a supplement to the approved plan would need to be submitted to FDA for review and approved before making changes to the display or distribution of required warnings on packages or the rotation of required warnings in advertisements. For a new brand, a new plan or a supplement to an approved plan would need to be submitted and approved before displaying or distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an approved plan for a new brand, manufacturers may reference in their initial plan "all brands" in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warnings for all brands.

Table 3.-- Estimated One-Time Reporting Burden ¹

Type of Plan	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial Plans	59	1	59	150	8,850
Supplements	30	1	30	75	2,250
Total					11,100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., OMB control numbers 0910-0671 (smokeless tobacco products) and 0910-0768 (cigars)) and 2017 Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) data.

As discussed in the Final Regulatory Impact Analysis (see section XIII; Ref. 16), based on 2017 TTB data, FDA estimates 59 entities will be affected by the rule. We estimate these 59 entities will submit a one-time initial plan, and it will take an average of 150 hours per respondent to prepare and submit a plan for packaging and advertising for a total of 8,850 hours. We estimate that about half of respondents will submit a supplement. If a supplement to an approved plan is submitted, FDA estimates it will take half the time per response. We estimate receiving 30 supplements at 75 hours per response for a total of 2,250 hours. FDA estimates that the total hours for submitting initial plans and supplements will be 11,100.

Section 1141.10(g)(4) would establish that each tobacco product manufacturer required to randomly and equally display and distribute required warnings on packaging or quarterly rotate required warnings in advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and this part must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy (or record) of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection would require that the record(s) be retained while in effect and for a period of not less than 4 years from the date of FDA's approval of the plan.

Table 4.--Estimated Annual Recordkeeping Burden ¹

Plan Records	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records	59	1.5	89	3	267
Total					267

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 3 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., OMB control numbers 0910-0671 and 0910-0768). Based on our estimates for the submission of initial plans and supplements (that all respondents will submit initial plans and about half of respondents will submit supplements), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA estimates that the total burden for this information collection is 11,367 hours (11,100 reporting hours + 267 recordkeeping hours).

FDA believes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB under the PRA because they do not constitute a "collection of information" under that statute (44 U.S.C. 3501-3521). Rather, these labeling statements are a "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

The information collection provisions in the final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of the final rule, FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information

collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XVI. Federalism

We have analyzed the final rule in accordance with the principles set forth in EO 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the EO and, consequently, a federalism summary impact statement is not required.

XVII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required. We received two comments related to tribal consultation and we respond to those comments in the following paragraphs.

(Comment 103) One comment objects to the rulemaking as a product of a court order rather than of deliberatively reasoned decision making, suggesting that due to the expedited schedule and lack of meaningful tribal consultation, the effectiveness of the rule in promoting public health and its disproportionate effect on tribal communities has not been fully considered.

The comment notes that, because the tribe relies in part on tobacco revenues to fund basic governmental services, the rule threatens to have an outsized effect on tribal manufacturers and requests that meaningful tribal consultation occur prior to finalizing the rule to discuss the impact and cost incurred by tribal governments.

(Response 103) FDA agrees that collaboration and consultation with federally recognized tribal governments, per the FDA Tribal Consultation Policy and EO 13175, is important. FDA engages with tribal stakeholders, including tribal government leaders, tribal health leaders, and public health professionals, about the implementation and enforcement of the Tobacco Control Act and related regulations by various methods (e.g., "Dear Tribal Leader" letters, All Tribes' Calls, formal and informal consultations as well as face-to-face meetings). We also encourage tribes to stay informed about developments related to tobacco products through our website (<https://www.fda.gov/TobaccoProducts>).

We disagree that the tribal consultation for the proposed rule was inadequate. There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers, which was considered as part of the Preliminary Regulatory Impact Analysis (<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>). In a "Dear Tribal Leader" letter dated August 15, 2019, FDA initiated consultation with federally recognized Indian tribes on the proposed rule and invited tribes to participate in an All Tribes' Call on September 19, 2019. The purpose of the call was to provide an overview of the proposed rule, answer questions, and hear tribal comments on the proposed rule. We provided contact information in the letter and during the call to help ensure that there was a mechanism to

address any further questions. We also encouraged tribes to submit written comments on the proposed rule and supporting documents such as the Preliminary Regulatory Impact Analysis.

(Comment 104) One comment supports the rule as a means to increase understanding of the negative health consequences of smoking and encourages FDA to ensure that these efforts reach American Indian/Alaska Native populations, which have the highest rates of cigarette smoking (Ref. 26) but lack understanding of the scope of the negative health consequences of smoking. The comment suggests that FDA partner with Urban Indian Health organizations to achieve the goals of this and any future goals, not as a substitute for tribal consultation but as a means to reach a target population.

(Response 104) We agree that the rule will promote greater public understanding of the negative health consequences of smoking. We note that in addition to this important rulemaking, FDA is developing other outreach with American Indian/Alaska Native partners.

XVIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 1141

Advertising, Incorporation by reference, Labeling, Packaging and containers, Tobacco, Smoking.

Therefore, under the Federal Cigarette Labeling and Advertising Act, the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1141 is revised to read as follows:

PART 1141--REQUIRED WARNINGS FOR CIGARETTE PACKAGES AND ADVERTISEMENTS

Subpart A--General Provisions

Sec.

1141.1 Scope.

1141.3 Definitions.

1141.5 Incorporation by reference.

Subpart B--Required Warnings for Cigarette Packages and Advertisements

1141.10 Required warnings.

1141.12 Misbranding of cigarettes.

Authority: 15 U.S.C. 1333; 21 U.S.C. 371, 374, 387c, 387e, 387i; Secs. 201 and 202, Pub. L. 111-31, 123 Stat. 1776.

Subpart A--General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of required warnings on cigarette packages and in advertisements for cigarettes.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer will not be in violation of § 1141.10 for packaging that:

(1) Contains a warning;

(2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) or this part.

(d) Section 1141.10(d) applies to a cigarette retailer only if that retailer is responsible for or directs the warnings required under § 1141.10 for advertising. However, this paragraph (d) does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning or has been altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act or this part.

§ 1141.3 Definitions.

For purposes of this part:

Cigarette means--

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product; or imports any cigarette that is intended for sale or distribution to consumers in the United States.

Package or *packaging* means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

§ 1141.5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the source listed in paragraph (b) of this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations.html.

(b) Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 1-888-463-6332. You may also obtain the material at <https://www.fda.gov/cigarette-warning-files>.

(1) "Required Cigarette Health Warnings, 2020", IBR approved for § 1141.10.

(2) [Reserved]

Subpart B--Required Warnings for Cigarette Packages and Advertisements

§ 1141.10 Required warnings.

(a) *Required warnings.* A required warning must include the following:

(1) One of the following textual warning label statements:

(i) WARNING: Tobacco smoke can harm your children.

- (ii) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- (iii) WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- (iv) WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- (v) WARNING: Smoking causes cataracts, which can lead to blindness.
- (vi) WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- (vii) WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- (viii) WARNING: Smoking causes head and neck cancer.
- (ix) WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- (x) WARNING: Smoking during pregnancy stunts fetal growth.
- (xi) WARNING: Smoking causes COPD, a lung disease that can be fatal.
- (2) A color graphic to accompany the textual warning label statement.
- (b) *Accurately reproduced.* Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5.
- (c) *Packages.* It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.
- (1) The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping.

(2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the front and rear panels of the carton and must comprise at least the left 50 percent of these panels.

(3) The required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(d) *Advertisements.* It is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement.

(2) The required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

(3) The text in each required warning must be in the English language, except as follows:

(i) In the case of an advertisement that appears in a non-English medium, the text in the required warning must appear in the predominant language of the medium whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning must appear in the same language as that principally used in the advertisement.

(4) For English-language and Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5.

(5) For non-English-language warnings, other than Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at § 1141.5, including the substitution and insertion of a true and accurate translation of the textual warning label statement in place of the English language version. The inserted textual warning label statement must comply with the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act, including area and other formatting requirements, and this part.

(e) *Irremovable or permanent warnings.* The required warnings must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

(f) *Sale or distribution.* No person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part, except as provided by § 1141.1(c) and (d).

(g) *Marketing requirements--(1) Random display.* The required warnings for packages specified in paragraph (a) of this section must be randomly displayed in each 12-month period, in

as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) *Rotation.* The required warnings for advertisements specified in paragraph (a) of this section must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributor, retailer to, and approved by, the Food and Drug Administration.

(3) *Review.* The Food and Drug Administration will review each plan submitted under this section and approve it if the plan:

(i) Will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) Assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.

(4) *Record retention.* Each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA-approved plan under section 4 of the Federal Cigarette Labeling and Advertising Act and this part must maintain a copy of such FDA-approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

§ 1141.12 Misbranding of cigarettes.

(a) A cigarette will be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette will be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(b) A cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

Dated: March 10, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

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